

Caleo[®] Neonatal Incubator

Operating Instructions
Software 1.n





NOTICE

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How to use these Operating Instructions

The headline ...

specifies the subject of the main chapter to help you find your way around quickly.

The page body ...

contains instructions for use of the device in a combination of text and illustrations. The information is translated directly into sequences of activities showing the user how to use the device.

The left-hand column ...

contains text

explaining the device and guiding the user directly to its uses through concise, ergonomically arranged instructions.

- Bullet points refer to individual actions.
- 1 numbers refer both to illustrations and the sequence of action when several steps are required to complete a task.

The right-hand column ...

contains illustrations

as a visual reference to the text, guiding the user to locate parts of the unit itself. Elements mentioned in the text are highlighted. Unnecessary details are omitted. Rendering of screen displays guide the user and allow to reconfirm actions performed.

Preparation

Before Using Incubator For the First Time
Installing Accessories

Preparation

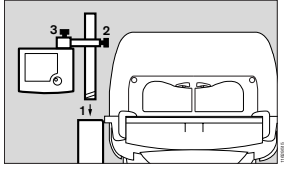
Before Using Incubator For the First Time

- Check that all packaging materials have been removed completely.
- Check that line voltage matches that specification on rating plate (see page 24).
- Check that the elevation above sea level has been entered correctly for the location of the incubator (see page 97).

- 1 Screw the extension pole fully into the frame base and tighten firmly. Check that it is securely held in place.
- 2 Slide holder over the pole and secure it at the required working height with the clamping screw.
- 3 Adjust control unit to the desired working position and clamp it securely to the holder with the locking screw.

CAUTION !

When mounting control unit to its pole, ensure that there is sufficient space to swivel the control unit. (see "Tilting the bed", page 43).



Installing Accessories

CAUTION !

Always verify that monitor shelves and other accessories are securely attached.

Always observe the following limits:

Maximum overall load must not exceed 60 kg (132 lbs) (see page 151).

For items attached to column on swivel shelves, do not exceed load of 3 kg (6.6 lbs).

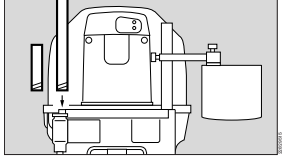
Accessory poles

CAUTION !

Maximum load for accessory poles is 5 kg (12 lbs).

Pole 38 mm/600 (2M 50 691), or alternatively,
Pole 38 mm/310 (2M 50 688)

- Remove cover plate from the frame base.
- Screw pole fully into the frame base and tighten firmly.
- Check that it is securely held in position.



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Important Safety Information – Intended Use

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Important Safety Information

Operator's Responsibility for Patient Safety

WARNING !

Strictly follow this Operator's Instruction Manual
Any use of the product requires full understanding and strict observation of all portions of these instructions.
This equipment is only to be used for the purpose specified under "Intended Use" (see page 12).
Observe all WARNINGS and CAUTIONS as rendered throughout this manual and on labels on the equipment.

The design of this equipment, the accompanying literature, and the labeling on the equipment take into consideration that the purchase and use of this equipment are restricted to trained professionals, and that certain inherent characteristics of the equipment are known to the trained operator. Instructions, warnings, and caution statements are limited, therefore, largely to the specifics of the Dräger design. This publication excludes references to various hazards which are obvious to a medical professional and operator of this equipment, to the consequences of product misuse, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. Draeger Medical, Inc. disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this product with other products whether supplied by Dräger or by other manufacturers if such a combination is not endorsed by Draeger Medical, Inc.

Patient monitoring

The operators of this infant incubator system must recognize their responsibility for choosing appropriate safety monitoring that supplies adequate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of different means ranging from electronic surveillance of equipment performance and patient condition to simple, direct observation of clinical signs. Responsibility for the selection of the best level of patient monitoring lies solely with the equipment operator.

Limitation of Liability

Draeger Medical, Inc.'s liability, whether arising out of or related to manufacture and sale of the goods, their installation, demonstration, sales representation, use, performance, or otherwise, including any liability based upon Draeger Medical, Inc.'s Product Warranty, is subject to and limited to the exclusive terms and conditions as set forth, whether based upon breach of warranty or any other cause of action whatsoever, regardless of any fault attributable to Draeger Medical, Inc. and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability, or otherwise).

THE STATED EXPRESSED WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR NONINFRINGEMENT.

Draeger Medical, Inc. shall not be liable for, nor shall buyer be entitled to recover any special incidental, or consequential damages or for any liability incurred by buyer to any third party in any way arising out of or relating to the goods.

Warranty

All Dräger products are guaranteed to be free of defects for a period of one year from date of delivery.

The following are exceptions to this warranty:

1. The defect shall be a result of workmanship or material. Defects caused by misuse, mishandling, tampering, or by modifications not authorized by Draeger Medical, Inc. or its representatives are not covered.
2. Rubber and plastic components and materials are warranted to be free of defects at time of delivery. Any product which proves to be defective in workmanship or material will be replaced, credited, or repaired with Draeger Medical, Inc. holding the option. Draeger Medical, Inc. is not responsible for deterioration, wear, or abuse. In any case, Draeger Medical, Inc. will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

1. Draeger Medical, Inc. or its authorized representative must be promptly notified, in writing, upon detection of the defective material or equipment.
2. Defective material or equipment must be returned, shipping prepaid, to Dräger or its factory authorized service center.
3. Examination by Dräger or its factory authorized service center must confirm that the defect is covered by the terms of this warranty.
4. Notification in writing, of defective material or equipment must be received by Dräger or its factory authorized service center no later than two (2) weeks following expiration of this warranty.

The above is the sole warranty provided by Draeger Medical, Inc.

No other warranty expressed or implied is intended.

Representatives of Dräger are not authorized to modify the terms of this warranty.

Draeger Medical, Inc., Telford, PA

Definitions

WARNING !

A **WARNING** statement refers to conditions with a possibility of personal injury if disregarded.

CAUTION !

A **CAUTION** statement designates the possibility of damage to equipment if disregarded.


NOTE: A **NOTE** provides additional information intended to avoid inconveniences during operation.

Inspection	= examination of actual condition
Service	= measures to maintain specified condition
Repair	= measures to restore specified condition
Maintenance	= inspection, service, and repair, where necessary
Preventive Maintenance	= Maintenance measures at regular intervals

Typing conventions in this manual

Display messages are printed as »message«, e. g:
»confirm new mode with rotary knob«

Controller keys are designated as »**Key Name**«, e.g.
»**man.**«

 indicates a reference to the operating manual on the incubator, e.g. for a control element.

Summary of WARNINGS and CAUTIONS

WARNING !

Strictly follow this Operator's Instruction Manual
Any use of the product requires full understanding and strict observation of all portions of these instructions.
This equipment is only to be used for the purpose specified under "Intended Use" (see page 12).
Observe all WARNINGS and CAUTIONS as rendered throughout this manual and on labels on the equipment.

WARNING !

This device may only be used by properly trained personnel under the supervision of qualified medical personnel familiar with the currently known risks and benefits of using an infant incubator.

WARNING !

Dräger cannot warrant or endorse the safe performance of third party accessories for use with the Caleo incubator system.
Only use accessories that are qualified to the required specifications for an intended use in an oxygen enriched environment.

WARNING !

This device is to be used only in rooms with line power installations complying with national safety standards for hospital patient rooms.
(e.g., IEC/EN 601.1, "Safety of Medical Equipment).
To maintain grounding integrity, connect only to a "hospital grade" receptacle.
Always disconnect supply before servicing.

WARNING !

DANGER, risk of explosion if used in the presence of flammable anesthetics.
This device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely.

WARNING !

The use of this device requires continuous supervision of the infant by trained nursing personnel in order to avoid immediate corrective action in situations with a risk of patient injury.

WARNING!

Mobile telephones must not be used within 10 meters (33 feet) of the incubator. Mobile telephones can interfere with the function of electromedical equipment and therefore endanger the patient!

CAUTION !

Restriction of Distribution

Federal Law and Regulations in the United States and Canada restrict this device to sale by or on the order of a physician.
This device for use only in health care facilities and to be used only by persons with specific training and experience in the use of the device.

CAUTION !

Maintenance

The device must be inspected and serviced at regular 1 year intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with DraegerService through your vendor.

For repairs of the Caleo incubators we recommend that you contact DraegerService.

Important Safety Information

Summary of WARNINGS and CAUTIONS

Precautions During Preparation

WARNING !

Always observe all precautions against fire hazards from oxygen (see page 53).

WARNING !

Always observe the maximum load of the infant bed (5 kg, 11 lbs).

WARNING !

Never leave infant unattended when access doors or hand ports are open to avoid any risk of an infant falling out of an incubator.

WARNING !

Never leave infant unattended when the bed has been pulled out to avoid any risk of an infant falling out of an incubator.

WARNING !

Always ensure that hand port catches are securely engaged in order to avoid any risk of an infant falling out of an incubator.

WARNING !

Do not lean on the bed when it is pulled out. Equipment damage with risk of patient injury may result.

WARNING !

When opening and closing front door, avoid pinching or jamming hoses and cables in the attached double wall.

WARNING !

Always ensure that the bed is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.

WARNING !

Always ensure that both knobs of the access doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.
The red catch behind each knob must no longer be visible!

WARNING !

Do not use the X-ray drawer as a writing support or as a bed for the infant. Risk of equipment damage or patient injury.

WARNING !

When opening and closing side door, avoid pinching or jamming hoses and cables in the attached double wall.

WARNING !

Always ensure that the x-ray drawer is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.

WARNING !

Always ensure that both knobs of the side doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.
The red catch behind each knob must no longer be visible!

WARNING !

Do not reach between incubator housing and housing support while tilting the bassinets. Risk of injury!

WARNING !

Do not use any additives for water intended for humidifying the incubator.

WARNING !

Use only unopened original bags containing pure and sterile distilled water.

Do not use any additives for water intended for humidifying the incubator.

Water bags for humidification must not be confused with infusion solutions!

WARNING !

Connections to the integrated power strip should only be made by factory trained and authorized technical service personnel.

Output of the integrated power strip is not monitored!
Do not connect life support devices which do not have their own power failure alarm.

⚠ Do not exceed the maximum permissible power input for connected accessories (all 4 sockets together: max. 2A).

Do not exceed the maximum permissible total leakage current. For the leakage current of Caleo without socket strip (see "Technical Data", page 148).

WARNING !

Do not use a power outlet strip for supplying power to the Caleo incubator!

Connecting the incubator via a power outlet strip may, in case of failure of the protective earth conductor, cause patient leakage currents to rise above permitted limits with a risk of electric shock to the patient.

WARNING!

The Caleo incubator is ready for operation only when all checks have been performed successfully.

CAUTION !

When mounting control unit to its pole, ensure that there is sufficient space to swivel the control unit (see "Tilting the bed", page 43).

CAUTION !

Always verify that monitor shelves and other accessories are securely attached.

Always observe the following limits:

Maximum overall load must not exceed 60 kg (132 lbs) (see page 151).

For items attached to column on swivel shelves, do not exceed load of 3 kg (6.6 lbs).

CAUTION !

Maximum load for accessory poles is 5 kg (12 lbs).

CAUTION !

Maximum load for swivel tray is 3 kg (6.6 lbs).

Ensure sufficient space for swivelling!

CAUTION !

Do not install incubator controller on telescoping column.

CAUTION !

Maximum load for instrument tray is 2 kg (4.4 lbs).

CAUTION !

Maximum load for notebook holder is 3 kg (6.6 lbs).

CAUTION !

Maximum load for monitor shelf is 20 kg (44 lbs).

Vertical distance between monitor shelf and stand must not exceed 20 cm (8 inches).

CAUTION !

Always check that connecting O₂ supply hose is of sufficient length when using independent O₂ flowmeter, allowing for the height adjustments of the bassinet.

CAUTION !

Maximum pressure of oxygen supply: 73 psi (500 kPa).

CAUTION !

Maximum load for drawer is 7 kg (15 lbs).

Important Safety Information

Summary of WARNINGS and CAUTIONS

CAUTION !

Maximum load for drawer is 7 kg (15 lbs).

CAUTION !

Always take care not to damage sensor unit inside the incubator when manipulating canopy !


CAUTION !

Cables and hoses must be sufficiently long to avoid kinking, tear or pinching when adjusting the incubator height.
Do not store anything underneath the drawer.

CAUTION !

Cables and hoses must be carefully routed to avoid kinking, tear or pinching when adjusting the incubator tilt angle!

CAUTION !

 Exclusively use sterile distilled or demineralized water for humidifying the incubator!

Precautions During Operation

WARNING !

Make sure that all hoses and cables are routed correctly and safely without obstruction! Otherwise:
Risk of extubation! Danger of disconnection!

WARNING !

Never leave infant unattended when the canopy, double walls, front door, or hand ports are open, when the bed has been pulled out or when access grommets have been removed. Risk of patient injury. Infant may fall out of the incubator.

WARNING !

Always observe the maximum load of the patient bed (5 kg, 11 lbs).
Do not lean on or apply weight to the bed when it has been pulled out.

WARNING !

Avoid additional external heat sources, such as direct sunlight, spot lamps, and electric pads or blankets. They cause the air temperature inside the incubator to increase in an uncontrolled fashion.

WARNING !

The infant's temperature must be regularly monitored with an independent thermometer.

WARNING !

It is the responsibility of the attending physicians to draw conclusions from the measured skin temperature.

WARNING !

Do not use skin temperature control mode for infants in shock, as their skin temperature is much lower than normal. Skin temperature control would increase the incubator air temperature too much, resulting in the risk of overheating the infant.

We recommend operating the Caleo incubator in air temperature control mode when caring for patients with such conditions – see page 57.

WARNING !

Do not use skin temperature control mode for infants with a fever, since their skin temperature is much higher than normal. Using skin temperature control would reduce the incubator air temperature too much, resulting in the risk of hypothermia.

WARNING !

Skin temperature control mode must not be used on twins, since Caleo controls only the temperature for one infant. Risk of hypothermia or overheating. Always use air temperature control mode when caring for twins.

WARNING !

Do not confuse skin sensor probe positions on the infant's body! The yellow skin temperature sensor (T1) is used for skin temperature control. Inappropriate positioning of this sensor could lead to overheating of the infant.

WARNING !

Do not place any blankets or sheets over the hot air vent. The temperature control system would be disrupted, causing a risk of overheating or burn if air from the hot air vent is channelled directly to the infant.

WARNING!

Cleaning mode may only be used while Caleo is not occupied by a patient.
After use, allow Caleo to cool down before dismantling.
Risk of burns when touching the heater!

WARNING !

During a power failure, the lack of fresh air supply may cause an elevated CO₂ concentration inside the patient capsule. Risk of CO₂ poisoning.

WARNING !

Beware of cross-infections when treating twins!

WARNING !

Fire hazards from oxygen !

- No open flames or cigarettes ! Textiles, plastics, and oils readily ignite in an oxygen enriched atmosphere and burn with great intensity.
- Keep oxygen valves, connections, and seals free from oil and grease.
- Open valves on O₂ cylinders slowly
- Do not operate Caleo in the presence of flammable anesthetics or disinfectants. Risk of explosion!
- Do not use or store flammable liquids such as alcohol, ether, or acetone inside the Caleo incubator.
- Do not use electrical equipment inside the patient capsule unless this equipment is expressly designed for use in environments that present an explosion hazard.

WARNING !

Due to the physiological risks from O₂, it is mandatory to monitor O₂ concentrations continuously during the administration of O₂, either using the integrated O₂ measurement and control system or an independent O₂ analyzer.

WARNING !

Always take into consideration the physiological risks from the administration of oxygen.
Elevated oxygen concentrations inside the incubator may only be used by or on the order of a physician.
It is absolutely essential that such oxygen therapy be selected and controlled on the basis of the arterially measured oxygen partial pressure in the infant's blood.
This is the only way to minimize the risk of both hyperoxemia (with potential for damage to the eyes by retrolental fibroplasia) and hypoxemia (which might contribute to intraventricular hemorrhage and damage to the infant's brain).

WARNING !

Medicated aerosols and similar substances must not be nebulized in the patient capsule.
The mist of nebulized substances may impair the proper function of the incubator.

WARNING !

When using Kangaroo Mode, the temperature of the infant, who is outside the controlled climate of the incubator, must be monitored constantly.
Particular attention must be paid to critical care patients' vital parameters, especially a critical O₂ partial pressure.
Ensure that all cables and hoses are routed correctly and safely.

WARNING !

Infant temperature must be monitored with particular care during phototherapy. Absorption of light through the infant's skin will supply heat to the patient which may increase infant temperature.

WARNING !

During phototherapy, the supply of fluids to the infant must be increased, e.g. by parenteral infusion, to compensate for the increased water loss.

WARNING !

Never cover phototherapy lamp or incubator canopy with cloths, aluminium foil or other materials with the intention to boost the phototherapeutic effect. A heat build-up will likely result with the danger of overheating the infant, because the incubator cannot be adequately cooled with ambient air under these conditions.

WARNING !

Always use eye protection for the infant when using phototherapy.

WARNING !

Ensure that the ventilator circuit and all other cables, hoses and tubing are routed correctly and safely.
Danger of extubation and disconnection!
Hoses and/or cables are at risk of being trapped when tilting the Caleo, adjusting the height, and when opening and closing the front door.

WARNING !

Caleo is to be used only in rooms with line power installations that comply with national safety standards for hospital patient rooms (e.g., IEC/EN 601.1, "Safety of Medical Equipment).
To maintain grounding integrity, connect only to a "hospital grade" receptacle.
Always disconnect supply before servicing.

WARNING !

Do not use a power outlet strip for supplying power to the Caleo incubator!
Connecting the incubator via a power outlet strip may, in case of failure of the protective earth conductor, cause patient leakage currents to rise above permitted limits with a risk of electric shock to the patient.

WARNING!

Cleaning mode may only be used while Caleo is not occupied by a patient.

WARNING!

Risk of burns upon contact with the heater!
Do not disassemble Caleo while in cleaning mode.

WARNING !

While alarm suppression is active, the operator of the incubator must still assume responsibility for proper patient care and safety in the event of an alarm. Failure to identify and correct alarm situations may result in patient injury.

WARNING !

Only use auxiliary electromedical equipment which complies with national safety standards for hospital patient rooms (e.g., IEC/EN 601.1, "Safety of Medical Equipment", UL 544).
When using the integrated power strip to connect auxiliary devices, always observe total leakage current and current consumption limits!
(See "Technical Data", page 148.)

WARNING !

The output of the integrated power strip is not monitored!
Do not connect life support devices which do not have their own power failure alarm.

WARNING !

Mobile telephones must not be used within 10 meters (33 feet) of the incubator. Mobile telephones can interfere with the functioning of electromedical equipment and therefore endanger the patient.

WARNING !

Regularly measure infant temperature!
Do not leave canopy open for any length of time, otherwise the air temperature inside the incubator will drop.

WARNING !

When the extended setpoint range for air temperature is used, particular care must be taken to monitor infant temperature.

WARNING !

Monitor infant constantly when canopy, doors, or hand ports are open, to ensure infant cannot fall out of the incubator.

WARNING !

Always verify that skin temperature sensor probe is specified and approved for use with Dräger Caleo.

WARNING !

Do not use skin temperature sensors to measure rectal (central) temperature!
Do not locate sensor under the infant, otherwise measurement and control would be performed with reference to infant central temperature instead of skin temperature.

WARNING !

Regularly check that skin temperature sensor is properly attached to the infant's skin! A skin temperature probe that has fallen off would be measuring air temperature with a risk of overheating the infant (although the air temperature would not rise above 39 °C).

WARNING !

When the extended setpoint range for skin temperature is used, particular care must be taken to monitor infant temperature.

WARNING !

As long as 3 dashes remain on screen while the incubator is operated in skin temperature control mode, Caleo will not heat. Infant may become hypothermic.

WARNING !

Always keep in mind the physiological risks and fire hazards associated with the use of high O₂ concentrations.

CAUTION !

Use caution when moving the incubator over uneven surfaces, e.g. rough pavement outside the hospital or into an elevator, as castors may become damaged or dislodged.

CAUTION!

Never cover the sensor unit or hang anything from the openings in the sensor unit. Keep these openings free from dirt.

CAUTION !

Only use phototherapy units supplied with their own stand. Do not put phototherapy devices directly on Caleo canopy.

Precautions During Care

WARNING !

Always follow accepted hospital procedures for handling equipment contaminated with body fluids.

WARNING !

Always disconnect power supply before cleaning and disinfecting.

WARNING !

Risk of burns from heater!
When the incubator is closed, the heater is still hot enough to inflict serious burns for a long time after switching off (70 °C = 158 °F after 1 hour).

WARNING !

Always disconnect all supplies before disassembly.

WARNING !

Risk of burns upon contact with the heater.
Allow Caleo to cool down before further disassembly.

WARNING !

The incubator is ready for operation only when all checks have been carried out successfully.

WARNING !

Always ensure that both knobs of the access doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.
The red catch behind each knob must no longer be visible!

WARNING !

Always ensure that both knobs of the side doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.
The red catch behind each knob must no longer be visible!

Precautions During Maintenance

WARNING !

Always ensure that the bed is pushed all the way in!
Otherwise the ducted flow of warm air will be interrupted,
and the infant may be warmed or cooled excessively.

CAUTION !

Certain components of the Caleo incubator consist of materials that are sensitive to certain organic solvents sometimes used for cleaning and disinfecting (e.g., alcohols, phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.). Exposure to such substances may cause damage that is not always immediately recognized. Sterilization of the incubator or components with ethylene oxide (EtO) or disinfection with formaldehyde is also not recommended.

CAUTION !

U-grommets cannot be autoclaved at 134 °C (273 °F).

CAUTION !

Take care not to damage the sensor unit when removing patient bed.

CAUTION !

Do not allow any moisture to enter the sensor unit.
Do not disinfect sensor unit by immersion or spraying.
Sensor damage may result.

CAUTION !

Do not allow any moisture to enter the control panel.
Do not disinfect control panel by immersion or spraying.
Equipment damage may result.

CAUTION !

Ensure that only recommended cleaning agents and disinfectants are used!
The acrylic and Makrolon material may develop stress cracks if other agents, such as alcohol, are used.
Do not use UV radiation on the incubator. This also may cause cracks in the acrylic parts.

WARNING !

To avoid any risk of infection, clean and disinfect incubator and accessories before any maintenance according to established hospital procedures – this applies also when returning units or parts for repair.

WARNING !

In order to avoid risk of electric shock, always disconnect power supply before starting any maintenance procedures.

WARNING !

Never operate the Caleo incubator if it has suffered physical damage or does not seem to operate properly.
We recommend that you contact DraegerService for maintenance service for the Caleo incubator.

WARNING !

Treatment of batteries and O₂ sensors
— Do not throw into fire! Risk of explosion.
— Do not force open! Cells contain corrosive acid that may cause caustic burns.
— Do not attempt to recharge battery. Risk of explosion.

CAUTION !

For disposal of batteries and O₂ sensors follow all local, state, and federal legislation with respect to environmental protection.

CAUTION !

The device must be inspected and serviced at regular 1 year intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with DraegerService through your vendor.

For repairs of the Caleo incubators we recommend that you contact DraegerService.

Intended Use

WARNING !

This device may only be used by properly trained personnel under the supervision of qualified medical personnel familiar with the currently known risks and benefits of using an infant incubator.

Applications

Caleo is an infant incubator system for premature babies and sick infants up to a body weight of 5 kg (11 lbs) or a body length of 55 cm (22 inches), providing a controlled environment of warmth, humidity*, and elevated O₂ concentration* in the patient area. The total body weight when treating twins is limited to 5 kg (11 lbs).

Caleo is intended for use in clinical environments where premature babies or infants are treated who require a controlled climatic environment.

Options for nursing and therapy:

- Convective heat therapy through control of incubator air temperature or infant skin temperature
- Humidification of the incubator air
- O₂ therapy through controlled elevation of the O₂ concentration in the patient environment
- Nursery and intensive care via hand ports or two large access doors
- Pivoting bed for raising and lowering the infant's head (Trendelenburg and anti-Trendelenburg position)

With monitoring for:

- Air temperature
- Skin temperature
- Relative humidity
- O₂ concentration
- Weight*

WARNING !

Dräger cannot warrant or endorse the safe performance of third party accessories for use with the Caleo incubator system.

Only use accessories that are qualified to the required specifications for an intended use in an oxygen enriched environment.

Restrictions of Use

CAUTION !

Restriction of Distribution

Federal Law and Regulations in the United States and Canada restrict this device to sale by or on the order of a physician.

This device for use only in health care facilities and to be used only by persons with specific training and experience in the use of the device.

WARNING !

This device is to be used only in rooms with line power installations complying with national safety standards for hospital patient rooms (e.g., IEC/EN 601.1, "Safety of Medical Equipment).

To maintain grounding integrity, connect only to a "hospital grade" receptacle.

Always disconnect supply before servicing.

WARNING !

DANGER, risk of explosion if used in the presence of flammable anesthetics.

This device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely.

WARNING !

The use of this device requires continuous supervision of the infant by trained nursing personnel in order to avoid immediate corrective action in situations with a risk of patient injury.

WARNING!

Mobile telephones must not be used within 10 meters (33 feet) of the incubator. Mobile telephones can interfere with the function of electromedical equipment and therefore endanger the patient!*

- * Dräger medical equipment conforms to the interference immunity requirements laid down in product-specific standards or in EN 60601-1-2 (IEC 60601-1-2). However, depending on the design of a mobile phone and the use situation, field strengths exceeding the values laid down in the specified standards may be generated in the immediate vicinity of mobile phones, thereby causing interference and malfunctions.

* Available option

What's What / Operating Concept

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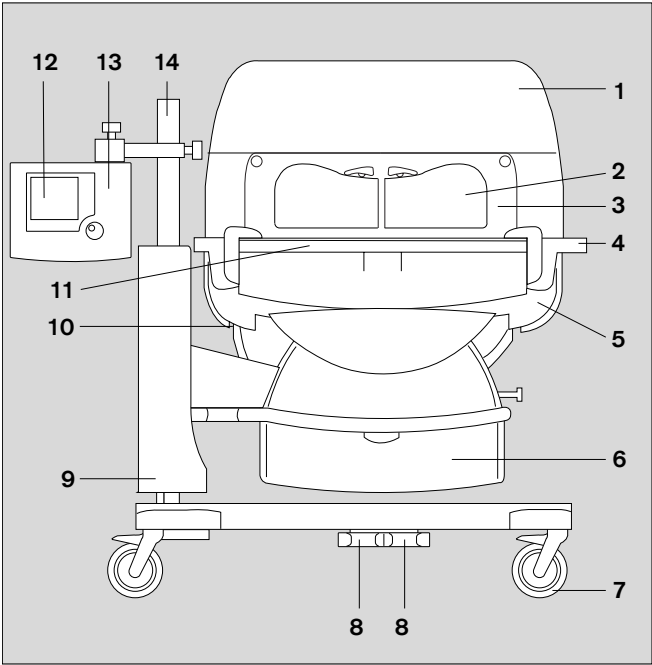
Control Unit 27

Screen 28

What's What

Front View

- 1 Canopy
- 2 Hand port
- 3 Front door
- 4 Transport handle
- 5 Bassinet frame
- 6 Drawer (2M 50 565)*
- 7 Castors
- 8 Pedals for height adjustment*
- 9 Height adjustable column*/ bassinet mount
- 10 Connection for water heater (luer lock)*
- 11 X-ray drawer / slide-out bed
- 12 Display
- 13 Control unit
- 14 Upright mounting support

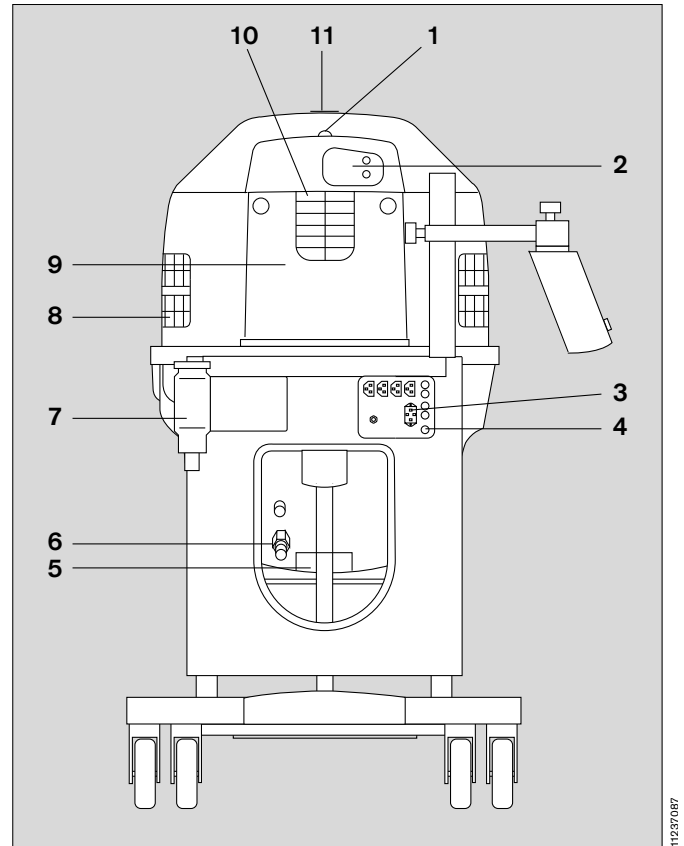


11137087

* Available option

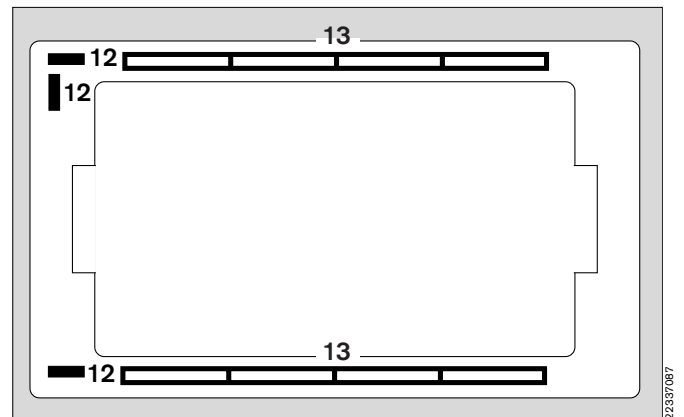
Side View, Connections

- 1 Central alarm light
- 2 Sensor unit, temperature sensor connections
- 3 Line power connection
- 4 On/off switch
- 5 Air intake filter (MX 17 015)
- 6 O₂ connection for O₂ control*
- 7 Water container (2M 50 040)*
- 8 Twin access U-grommets (2M 50 385)
- 9 Side door
- 10 U-grommets (2M 50 412)
- 11 Feeding grommet, hood (2M 50 352)



Top View

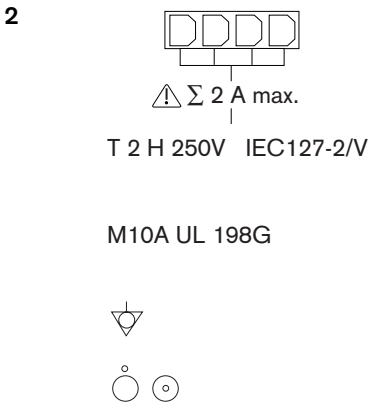
- 12 Leveling guides
- 13 Heating air vents



Labels



Connections for skin temperature sensors, page 62

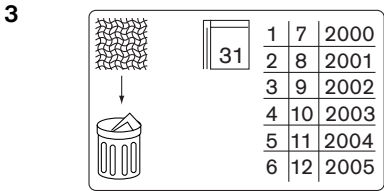


auxiliary power strip, page 45, Technical Data, page 148

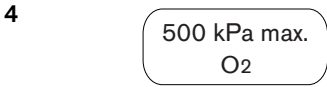
Type designation for fuses for auxiliary power strip
Type designation for system fuses

Equipotential bonding
On/off switch, page 56

ID/rating plate



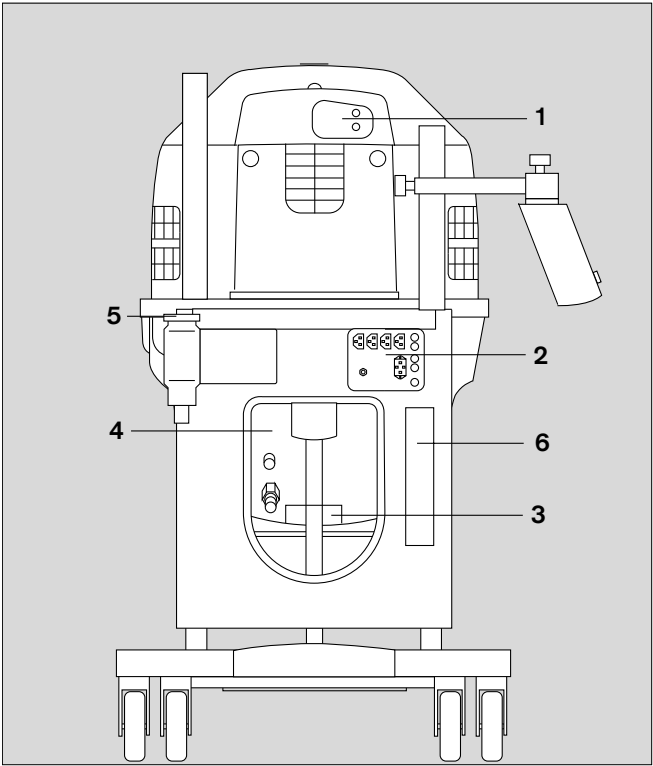
Filter label, exchange filter monthly, see page 109



page 34



page 44



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6

Caleo Infant Incubator**Quick Reference**

For detailed information, always refer to Caleo Operating Manual !

Before use, check device according to Instructions in Operating Manual.



Switch on device (rear side of mobile stand).



Select control mode by pressing button.



Adjust settings with rotary dial knob.
Confirm settings by pressing dial knob.
See text messages in case of alarm.

DANGER!

Risk of explosion if used in the presence of flammable anesthetics.

WARNING - FIRE HAZARD!

Keep all sources of ignition out of the room in which the incubator is located.

Higher risk of ignition and fire in air enriched with oxygen.

All oxygen valves, connections and seals must be kept free of oil and grease.

Open valves slowly.

Do not use any electrical equipment inside the incubator other than equipment or instruments expressly designed and approved for use inside incubators.

WARNING!

Disconnect supply before servicing.

Repairs on this equipment to be performed by Draeger-Service or factory trained and authorized personnel only.

CAUTION!

Opening of covers by DraegerService or factory trained and authorized personnel only.

To maintain grounding integrity connect only a 'hospital grade' power outlet.

Federal (US) Law restricts this device to sale by or on the order of a physician.

WARNING!

Danger of patient injury: never leave infant unattended when doors or handports are open.

WARNING!

Check infant temperature and skin condition at regular intervals and adjust temperature setting to individual patient needs.

Check incubator temperature, incubator function, and temperature sensor attachment at regular intervals.

Improper attachment or location of the temperature sensor may cause cooling or overheating of the patient.

WARNING!

External radiant heat sources such as radiant heaters or sunlight may increase incubator air temperature above the set level

WARNING!

Never block or obstruct air vents! Risk of burning!


Draeger Medical, Inc.
3136 Quarry Road
Telford, PA 18969

Labels

- 1

Never leave baby unattended when doors are open !

page 52
- 2




Do not tilt canopy forwards,
page 38
- 3

⚠ WARNING!
Never block or obstruct air vents! Risk of burning!


page 23, page 135
- 4

Always close X-ray tray tightly !

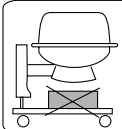
page 41
- 5

 max 5 kg, 11lbs

page 151
- 6

 max 7 kg, 14lbs


page 151
- 7



Use max.
6 min.
within
60 min.

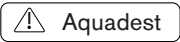
Do not place any objects on the base plate,
page 42

8



page 43


9




page 44

10

Batt.:
VARTA Lithium
3V CR 2NP



Baby
Link



RS232

Internal battery,
page 121

Interface connections,
page 150

11

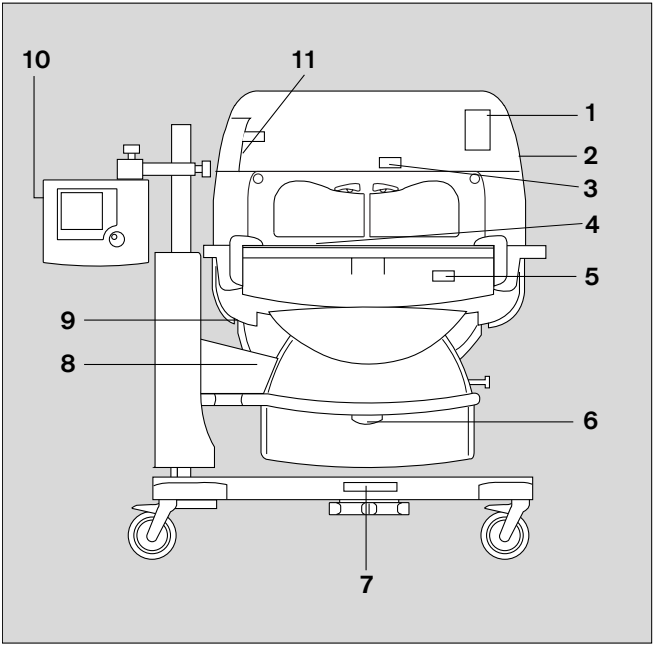
No spray disinfection!
Wipe disinfection only!

page 120

(inside)

Switch off device and allow heater to cool down for 90 min. before touching the surface!

page 93
page 110



Operating Concept

Control Unit

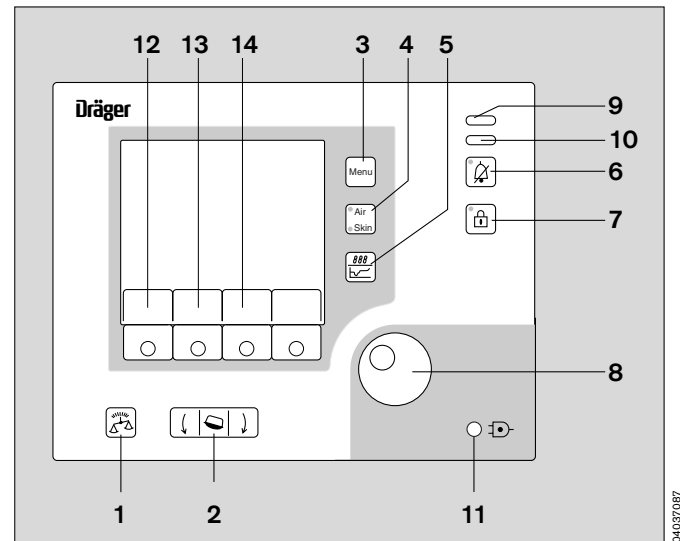
Hardkeys (fixed function keys)

serve to allow the user to call various functions of the Caleo incubator:

- 1 Scale*
- 2 Bed tilt
- 3 Menu list / configuration
- 4 Toggle key: air/skin temperature control
- 5 Trend display
- 6 Audible alarm silence
- 7 Keypad lock function
- 8 Rotary knob

Visual signals indicating alarm situations

- 9 Red alarm indicator LED
- 10 Yellow alarm indicator LED
- 11 Power failure alarm indicator



Softkeys (variable function keys)

guide the user through the unit's specific routines – from preparing for use to shutting down the incubator.

The active softkeys and their function change with the menu being used.

Only softkeys required for a currently active menu choice actually appear on screen. This helps to ensure that users don't become confused.

When a softkey is pressed, its function is activated and the relevant menu appears on screen.

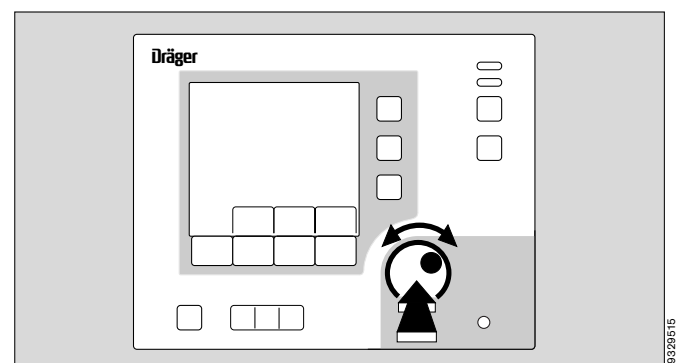
In the standard screen, the softkey layout is as follows:

- 12 Air/skin temperature
- 13 Humidity*
- 14 O₂*

Rotary knob

for performing selections/settings with just one control.

- Turn rotary knob to select.
- Press rotary knob to confirm selection.



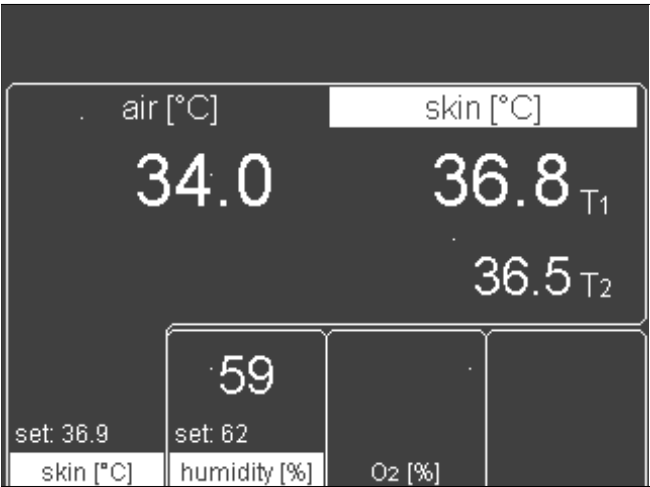
* Available option

Screen

By default, incubator parameters are displayed as numerical values (standard screen).

- Setpoint and measured values for air temperature or skin temperature
- Setpoint and measured values for relative humidity*
- Setpoint and measured values for O2 concentration*
- Alarm and warning messages

The screen display can also include a trend graph.



* Available option

Preparation / Checking Readiness For Operation

Contents

Preparation 30

Before Using Incubator For the First Time 30

Installing Accessories 30

Use of Doors, Ports, and Bed Adjusting Mechanism 36

Using Humidification Systems 44

Checking Readiness For Operation 46

Before Using For the First Time 46

Before Each Use 46

Preparation

Before Using Incubator For the First Time

Installing Accessories

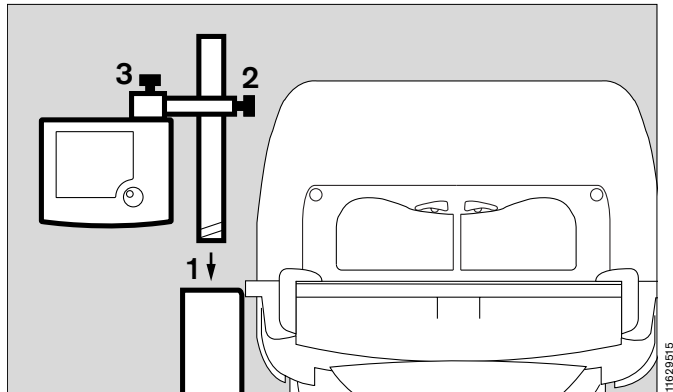
Preparation

Before Using Incubator For the First Time

- Check that all packaging materials have been removed completely.
 - Check that line voltage matches that specification on rating plate (see page 24).
 - Check that the elevation above sea level has been entered correctly for the location of the incubator (see page 97).
- 1 Screw the extension pole fully into the frame base and tighten firmly. Check that it is securely held in place.
 - 2 Slide holder over the pole and secure it at the required working height with the clamping screw.
 - 3 Adjust control unit to the desired working position and clamp it securely to the holder with the locking screw.

CAUTION !

When mounting control unit to its pole, ensure that there is sufficient space to swivel the control unit. (see "Tilting the bed", page 43).



Installing Accessories

CAUTION !

Always verify that monitor shelves and other accessories are securely attached.

Always observe the following limits:

Maximum overall load must not exceed 60 kg (132 lbs) (see page 151).

For items attached to column on swivel shelves, do not exceed load of 3 kg (6.6 lbs).

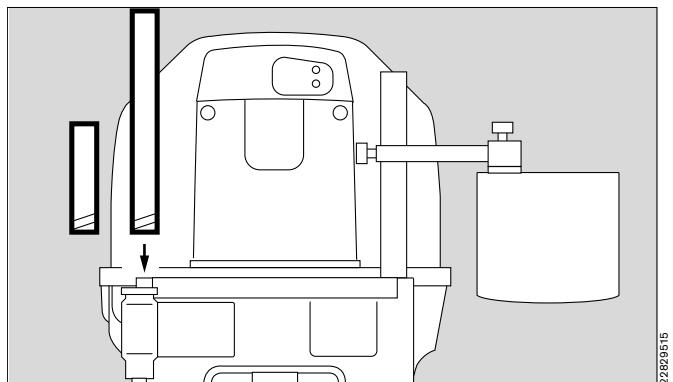
Accessory poles

CAUTION !

Maximum load for accessory poles is 5 kg (12 lbs).

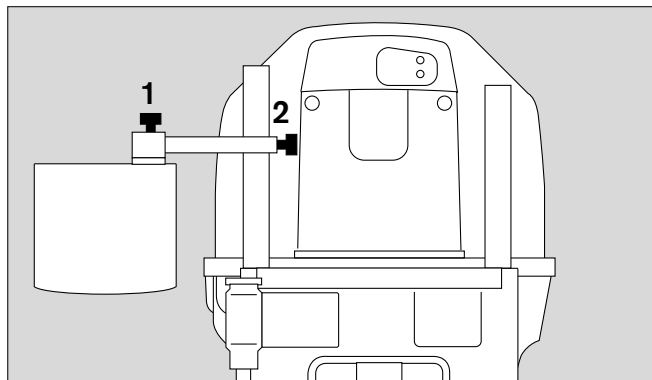
**Pole 38 mm/600 (2M 50 691), or alternatively,
Pole 38 mm/310 (2M 50 688)**

- Remove cover plate from the frame base.
- Screw pole fully into the frame base and tighten firmly. Check that it is securely held in position.



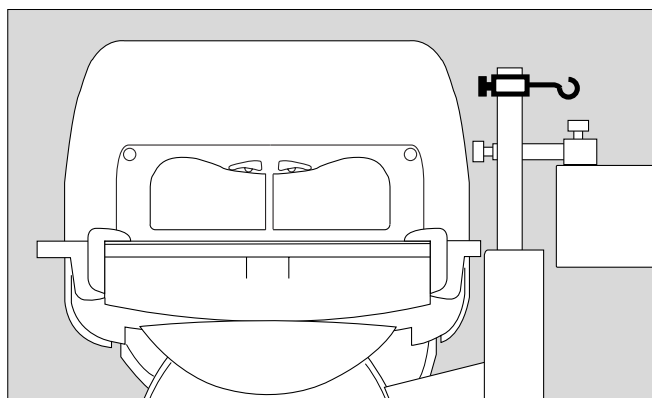
Moving the control unit to the opposite side

- 1 Loosen the clamping screw to remove control unit.
(Support control unit to prevent it from dropping once clamping screw is loosened)
- 2 Loosen the clamping screw to remove holder.
- Move holder to the other pole and set to the desired working height.
- 2 Tighten clamping screw to fix holder in position.
- 1 Tighten clamping screw to secure control unit to the holder.

**Infusion support attachment (2M 21 514)**

for pole, 38 mm

- Place pole clamp of the IV support on the upright mounting support.
- Secure IV support by tightening the clamp knob.

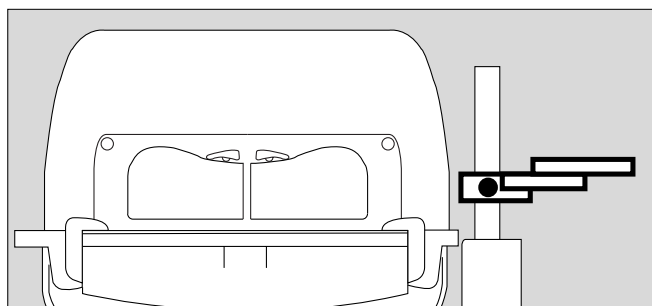
**Swivel tray (2M 21 186)**

For small items

CAUTION !

Maximum load for swivel tray is 3 kg (6.6 lbs).
Ensure sufficient space for swivelling!

- Place pole clamp of swivel tray onto the upright mounting support.
- Secure swivel tray by tightening the clamp knob.



Preparation

Installing Accessories

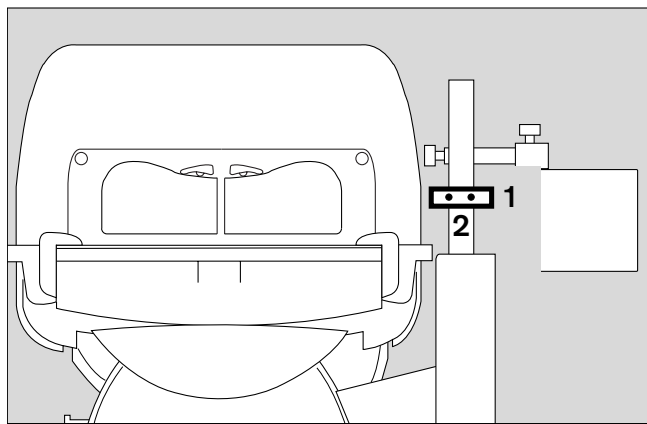
Compact mounting rail clamp (2M 85 337)

Maximum load 5 kg, for 38 mm pole.

For mounting such accessories as:

- O2 analyzer

- Adjust height of compact rail clamp considering the accessories to be installed to rail.
- 1 To attach compact rail to upright mounting support for accessories, slide over pole, and
 - 2 secure with screws.



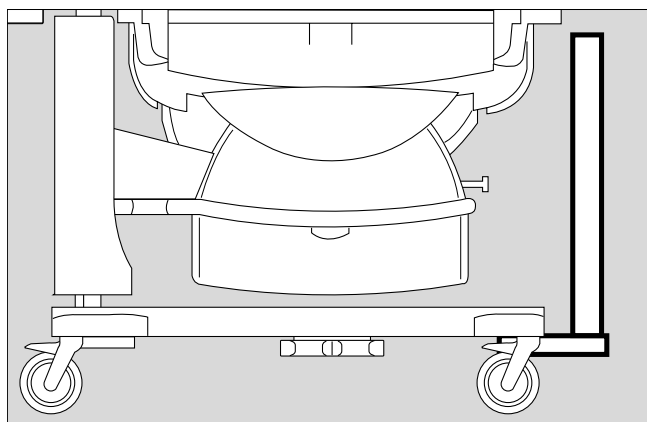
Base-mounted accessory pole (2M 50 680)

Maximum load 5 kg (11 lbs)

For mounting such accessories as:

- additional pole extensions (see page 33)
- swivel table (2M 21 186)
- monitor support shelf (2M 50 085)

Install in accordance with its separate Assembly Instructions.

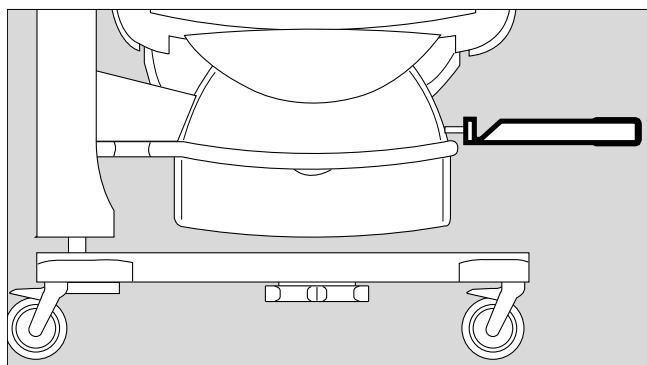


Instrument tray 3020 (M 24 678)

CAUTION !

Maximum load for instrument tray is 2 kg (4.4 lbs).

- Hook tray into handle rail and secure in position.

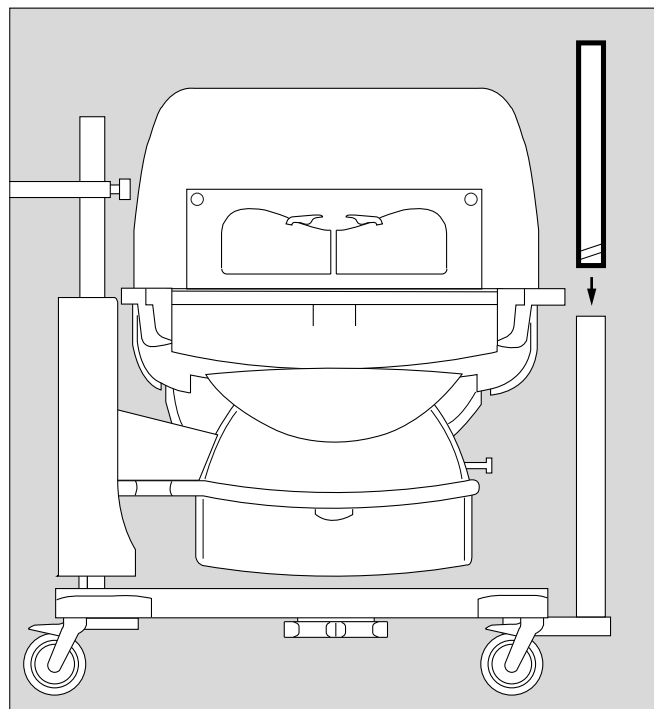


Pole extensions

The following poles can be used with the base-mounted accessory pole as extensions:

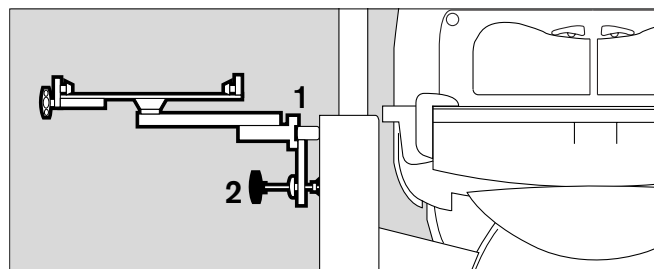
- Pole 38 mm/600 (2M 50 691) or
- Pole 38 mm/310 (2M 50 688) or
- Pole 25 mm/600 (2M 50 689).

- Screw pole into the base pole as far as it will go and tighten securely. Check that pole extension is securely held in place.

**Notebook holder (2M 22 171)****CAUTION !**

Maximum load for notebook holder is 3 kg (6.6 lbs).

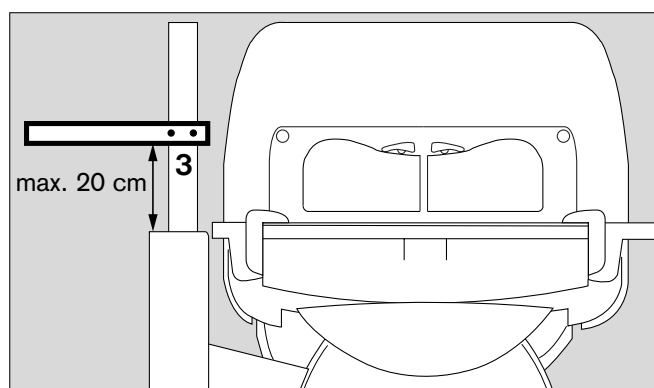
- 1 Secure holder to handle rail of Caleo.
 - 2 Align support with locking screw so that it is vertical.
- Tilt and turn mounting plate to check that holder is securely attached and swivel mechanism is functioning correctly.

**Monitor support shelf (2M 50 085)****CAUTION !**

Maximum load for monitor shelf is 20 kg (44 lbs).
Vertical distance between monitor shelf and stand must not exceed 20 cm (8 inches).

Shelf for monitor and ventilation equipment.
Before attaching the monitor shelf, install a second 38 mm pole (see page 30).

- To attach monitor support, slide plate over upright mounting support and
- 3 secure in position with screws.

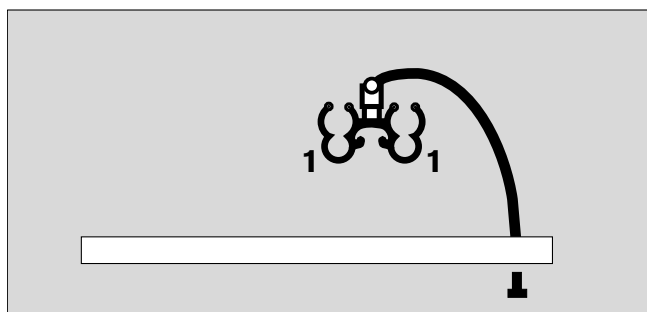


Flexible ventilator circuit support arm (84 11 075)

- Open front door.
- Raise bed and pull it out of the incubator.
- Push mattress slightly to one side.
- Place the support arm in one of the mounting holes in the bed and fasten from underneath with its locking screw.
- Re-install the bed in the incubator and close front door.

NOTE: The circuit support arm may be installed in any of the four corners of the bed.

- 1 Push ventilation circuits and cables into clip at the end of the support arm.



Preparing for O₂ therapy with O₂ control*

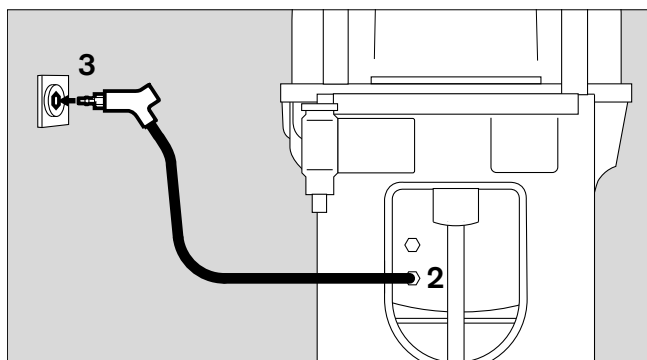
WARNING !

Always observe all precautions against fire hazards from oxygen (see page 53).

- 2 Screw the O₂ high pressure supply hose into the port underneath the incubator.
- 3 Connect quick connect probe to an outlet terminal of your medical gas pipeline O₂ supply. Use "standby position", if available (see respective Instructions for Use).

CAUTION !

Maximum pressure of oxygen supply: 73 psi (500 kPa).

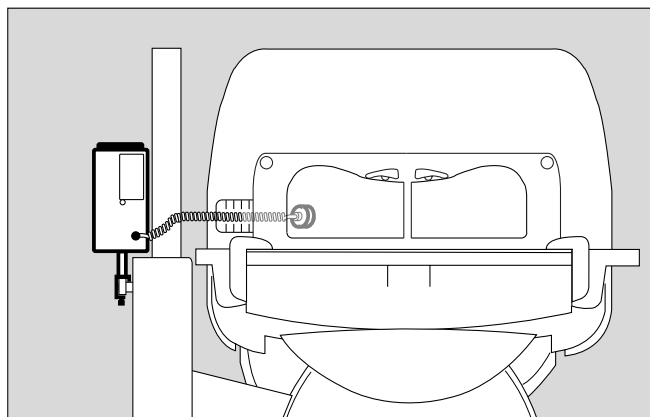


* Available option

O₂ analyzer

For monitoring O₂ concentration inside the incubator, install an O₂ analyzer with alarm limits:

- Attach O₂ analyzer to rail using the appropriate bracket.
- Place O₂ sensor capsule inside Caleo.
- Route sensor cable through one of the flexible hood grommets. Securely connect sensor plug to O₂ analyzer (see Instructions for Use of O₂ analyzer being used).



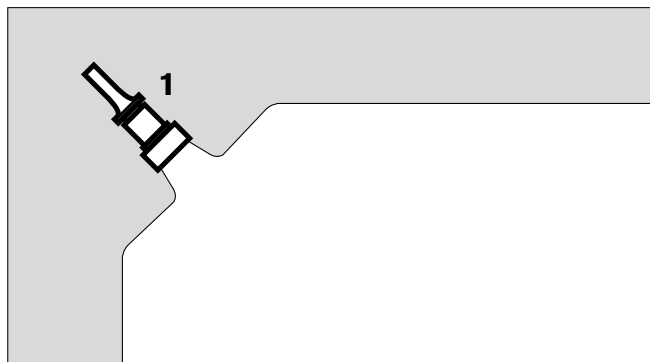
02829515

Vacuum mattress (2M 17 909)

The contour of the vacuum mattress can be altered as required and is maintained after evacuation of the air inside.

This allows to obtain extreme positions for special applications. The standard foam mattress can remain in the incubator while using the vacuum mattress.

- Open front door.
- Insert and pre-form vacuum mattress.
- Place infant on mattress and shape mattress around desired infant position.
- Connect vacuum mattress to the vacuum supply hose of the suction equipment.
- 1 Open valve and evacuate vacuum mattress.
- 1 Close valve and disconnect hose.
- Close front door.

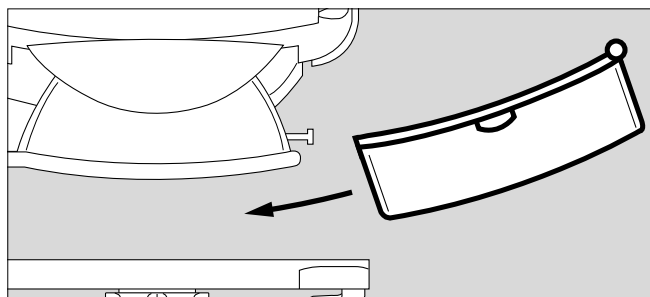


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Installing a drawer (2M 50 565)**CAUTION !**

Maximum load for drawer is 7 kg (15 lbs).

- To install, slide drawer into the groove in base frame.



118 20515

Use of Doors, Ports, and Bed Adjusting Mechanism

WARNING !

Never leave infant unattended when access doors or hand ports are open to avoid any risk of an infant falling out of an incubator.

Hand ports

To open hand ports:

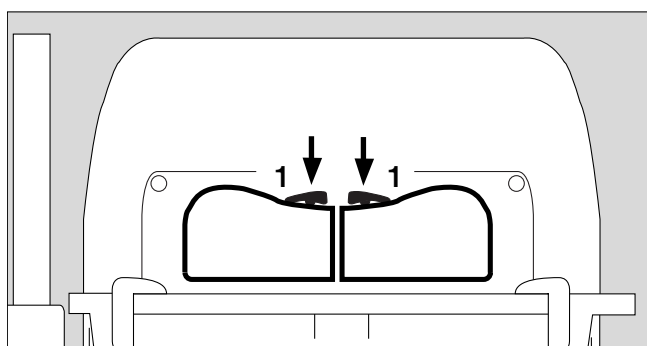
- 1 Press catch: The respective hand port swings open.

To close hand ports:

- Push hand ports back into place until catch engages.

WARNING !

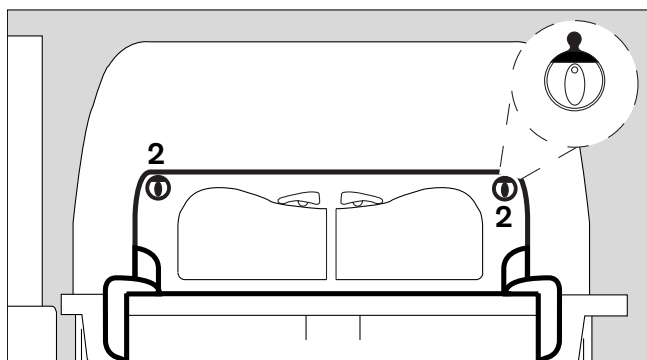
Always ensure that hand port catches are securely engaged in order to avoid any risk of an infant falling out of an incubator.



Front door

To open front door:

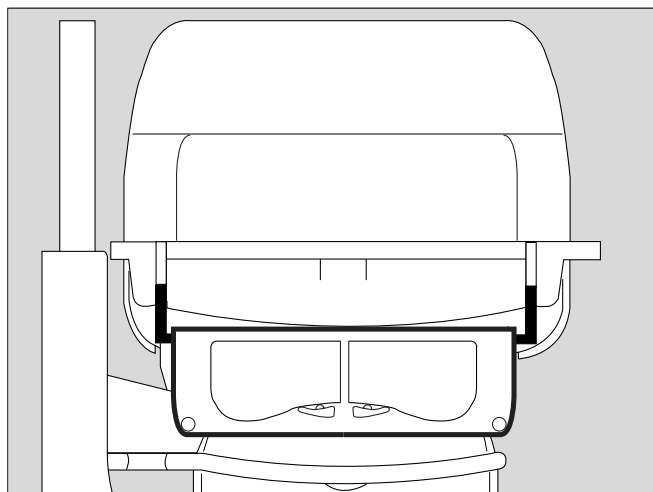
- 2 Turn the two knobs inwards to the vertical position. The red catch will now be visible.



- Lower front door until it hangs down vertically towards the floor.

WARNING !

When opening and closing front door, avoid pinching or jamming hoses and cables in the attached double wall.

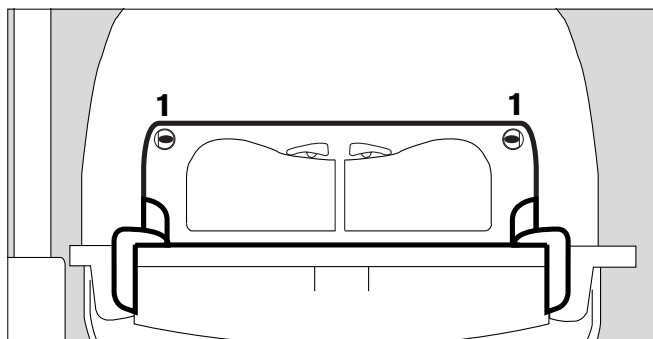


To close front door:

- Raise the front door and press into position,
1 Turn the two knobs outwards to the horizontal position until you feel them engage.

WARNING !

Always ensure that both knobs of the access doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.
The red catch behind each knob must no longer be visible!

**Side door**

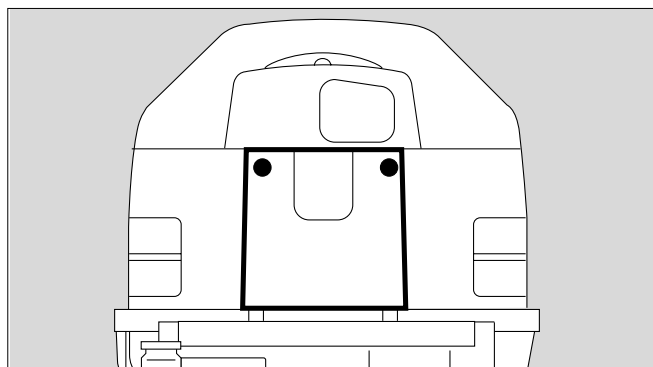
- The side door is opened and closed in the same way as the large access doors (see page 36).

WARNING !

When opening and closing side doors, avoid pinching or jamming hoses and cables in the attached double wall.

WARNING !

Always ensure that both knobs of the side door are engaged in position in order to avoid any risk of an infant falling out of an incubator.
The red catch behind each knob must no longer be visible!



Preparation

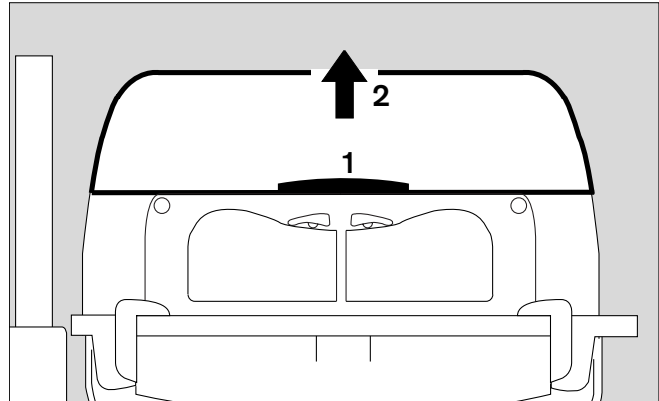
Use of Doors, Ports, and Bed Adjusting Mechanism

Canopy

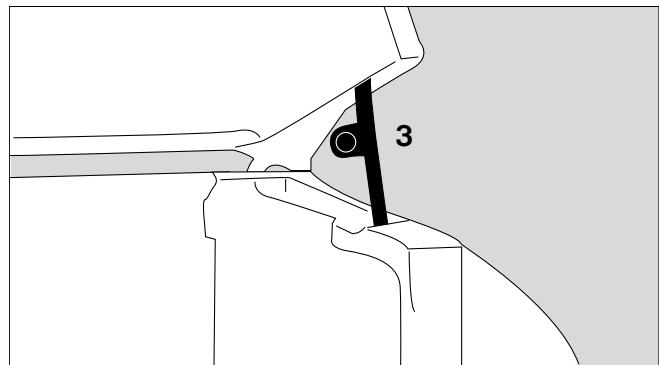
Opening the canopy:

- 1 Grasp handle on the canopy and
- 2 lift canopy upwards (approx. 60°).

NOTE: The canopy will only tilt back to a position where it is approximately upright. The hinges of the canopy will not allow it to tilt back beyond that point. Do not force the canopy further back than is required to engage the prop.



- 3 Raise canopy support prop, and lower canopy until prop is fixed in the slot of the canopy.



Closing the canopy:

- 1 Grasp handle on the canopy and raise it slightly.
- 3 Fold down the prop and
- close the canopy.

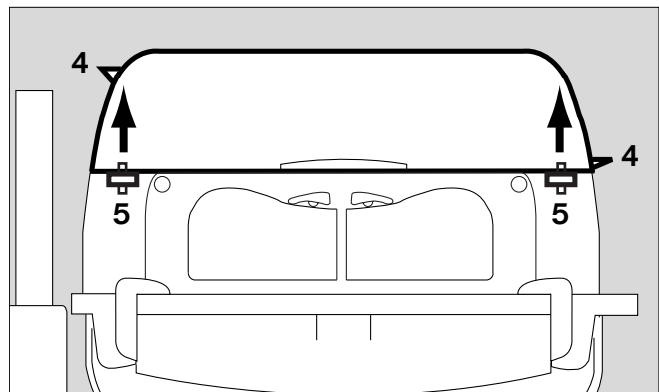
NOTE: The canopy can be opened from both sides.

Removing the canopy:

- 4 Grasp handles on the sides of the canopy with both hands.
- 5 Lift canopy horizontally off the supports.

Re-installing the canopy:

- 5 Place canopy horizontally, with the guide pins sliding into the holes in the canopy supports.



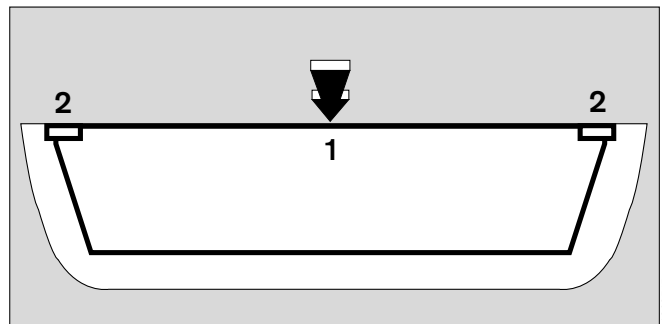
CAUTION !

Always take care not to damage sensor unit inside the incubator when manipulating canopy !

Double wall*

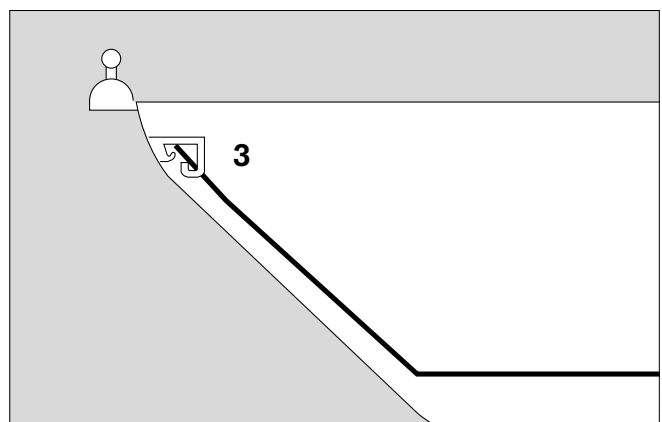
To remove double wall:

- Remove canopy and lay it upside down onto a soft, non-abrasive surface, e.g. a sheet or blanket.
- 1 Push double wall slightly inwards, and
- 2 Release double wall from the retaining clamps in the canopy.
- Pull double wall out of the canopy.



To install the double wall:

- Place canopy upside down onto a soft, non-abrasive surface.
 - Insert double wall into the canopy.
 - 3 On one side, fit retaining clamps of the canopy into the holes of the double wall.
 - Squeeze double wall slightly inwards and fit the retaining clamps on the second side of the canopy into the respective holes of the double wall.
 - Turn canopy upside again.
- All retaining clamps of the canopy must remain seated in the holes of the double wall.



* Available option

Preparation

Use of Doors, Ports, and Bed Adjusting Mechanism


Sliding out the bed

WARNING !

Always observe the maximum load of the infant bed (5 kg, 11 lbs).

- Open front door and fold it down.

Pull the bed out:


- 1 Turn both knobs to the horizontal  position,
- 2 Pull bed out towards the front as far as it will go, using the recessed handle or the knobs.

WARNING !

Never leave infant unattended when the bed has been pulled out to avoid any risk of an infant falling out of an incubator.

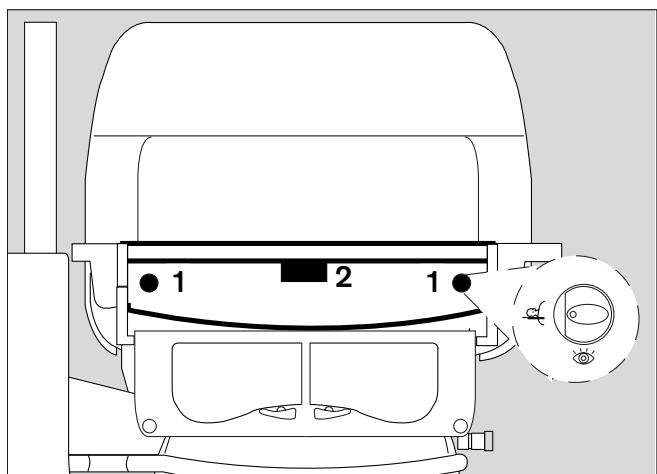
WARNING !

Do not lean on the bed when it is pulled out. Equipment damage with risk of patient injury may result.

- Upon completion of infant care procedures, push the bed back in until it engages. Turn knobs to the  position and close front door.

WARNING !


Always ensure that the bed is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.



Using the x-ray drawer

NOTE: The x-ray drawer can be pulled out while the front door is either open or closed.

To open the x-ray drawer:

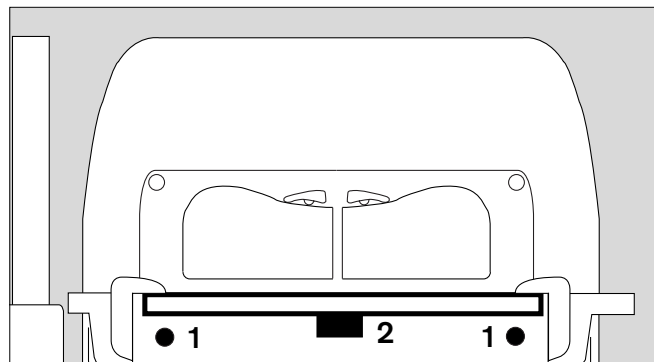
- 1 Turn both knobs to the vertical  position,
- 2 Pull drawer out by its recessed handle or by the knobs.

- Insert or remove the x-ray cassette.

NOTE: Recesses are provided in the x-ray drawer for positioning.

WARNING !

Do not use the x-ray drawer as a writing support or as a bed for the infant. Risk of equipment damage or patient injury.



To close the x-ray drawer:

- 2 Push drawer inwards under the bed until you can feel it click into place.

WARNING !

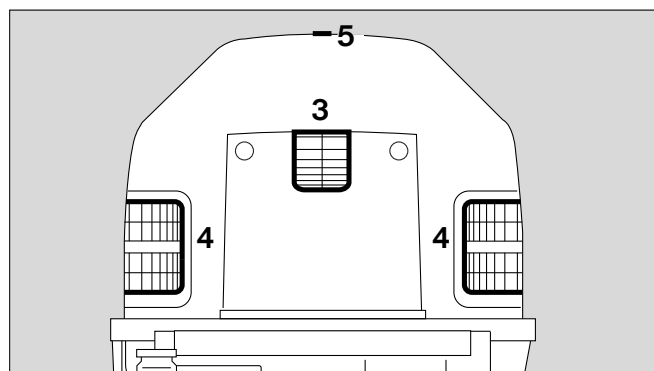
Always ensure that the x-ray drawer is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.

Incubator access grommets

- 3 Single U-grommet (2M 50 412)
- 4 Double U-grommets (2M 50 385)
- 5 Feeding grommet, hood (2M 50 352)

- Route cables, hoses, or tubes through the flexible grommets.

To route ventilator circuits and cables through Caleo, use the ventilation circuit support arm (see page 34).



Preparation

Use of Doors, Ports, and Bed Adjusting Mechanism

Drawer (2M 50 565)

Drawer for storing items required for nursing or treatment.

NOTE: The drawer is accessible from both sides.

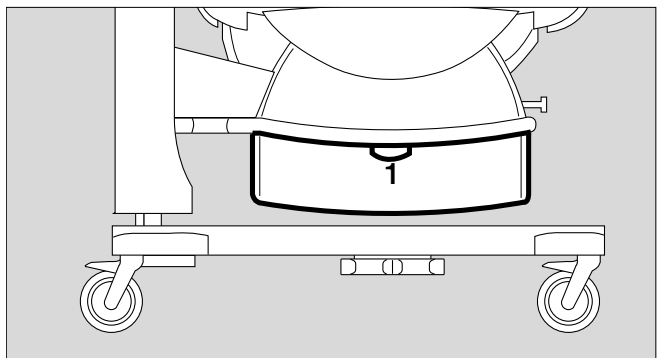
To open the drawer:

- 1 Grasp drawer by its handle and pull it out as far as it will go.

- Place the required material in the drawer.

To close the drawer:

- 1 Push drawer back in using the handle.



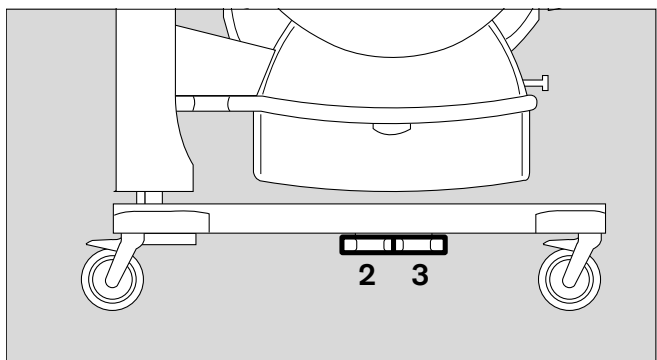
Mobile stand with height adjustable column*

To use the height adjustment feature:

- Switch on Caleo (see page 56).
- 2 Press left pedal – Caleo is lowered.
- 3 Press right pedal – Caleo is raised.
- Adjust to a comfortable working height.
- When the height does not change any further, the end position has been reached. Release pedal.

CAUTION !

Cables and hoses must be sufficiently long to avoid kinking, tear or pinching when adjusting the incubator height!
Do not store anything underneath the drawer.



NOTE: Adjustment of height and tilt angle cannot be performed at the same time

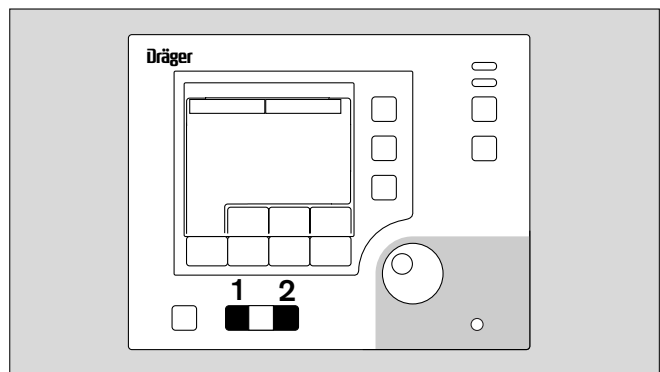
NOTE: The height adjustment is designed for intermittent duty (max. 6 minutes during one hour).

* Available option

Tilting the bed

To tilt the bed:

- Switch Caleo ON (see page 56).
 - 1 Press button to raise the control unit end of the bed.
 - 2 Press button to lower the control unit end of the bed.
 - Adjust the bed to the required tilt angle.
- When the tilt angle stops changing, the end position has been reached. Release button.



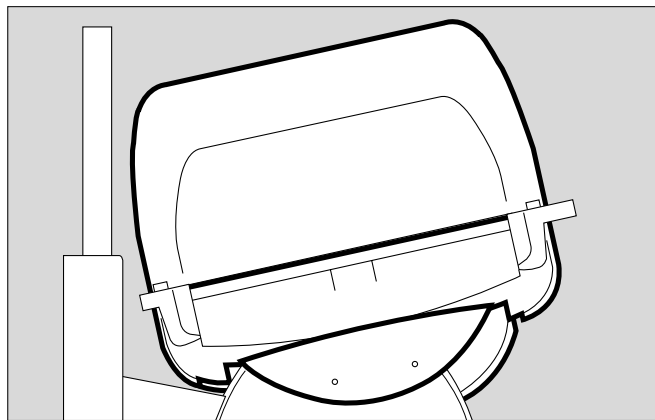
NOTE: The entire Caleo bassinet is tilted.

WARNING !

Do not reach between incubator housing and housing support while tilting the bassinet. Risk of injury!

CAUTION !

Cables and hoses must be carefully routed to avoid kinking, tear or pinching when adjusting the incubator tilt angle!



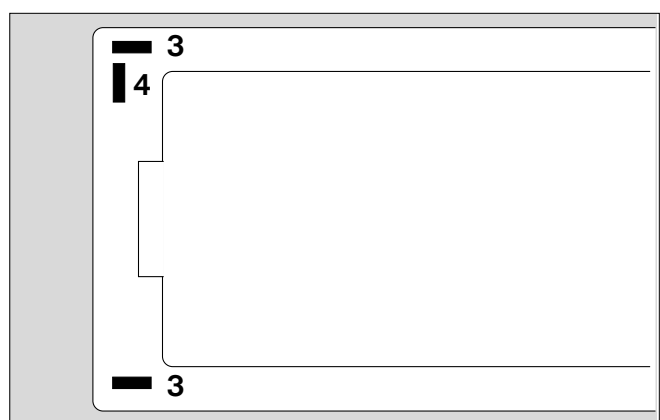
NOTE: Adjustment of height and tilt angle cannot be performed at the same time.

Adjusting the bed to the horizontal position

- Caleo must be switched on (see page 56).
- 1 Press button to raise bed on the control unit side.
- 2 Press button to lower bed on the control unit side.

The levels will indicate whether the bed is horizontal.

- 3 Level showing the horizontal position of Caleo in the transverse axis.
- 4 Level showing the horizontal position of Caleo in the longitudinal axis. When using the integrated infant scale (available option, see "Integrated Infant Scale", page 103), make sure that the incubator unit is on a level floor before making adjustments.



Using Humidification Systems

Using the water reservoir (2M 50 040)

- Disinfect hands.
- 1 Lift off cap to open water reservoir.
- Fill water container with distilled water.

CAUTION !

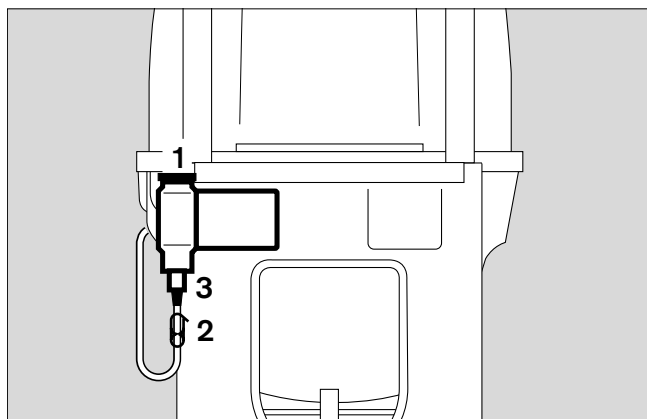
⚠ Exclusively use sterile distilled or demineralized water for humidifying the incubator!

WARNING !

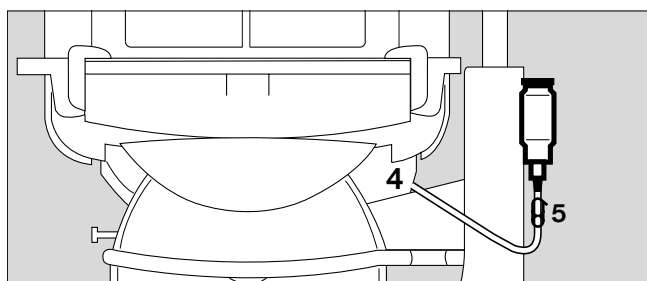
Do not use any additives for water intended for humidifying the incubator.

Filling capacity: **2.8 L** (note max. filling level mark)

- 1 Push cap back to close water reservoir.
- Prepare fresh water transfer set.
 - 2 Close clamp on water transfer set.
 - 3 Pierce water reservoir plug with pin of water transfer set.
 - 2 Open clamp on water transfer set.
 - Bleed water transfer set (let distilled water drain off).
 - 2 Close clamp on water transfer set.
- 4 Connect luer lock to Caleo.
 - 5 Open clamp on water transfer set.
- Switch on humidification module on Caleo and adjust humidity setpoint (see page 74).



09/29/15



18/02/15

Using a water bag

CAUTION !

⚠ Exclusively use sterile distilled or demineralized water!

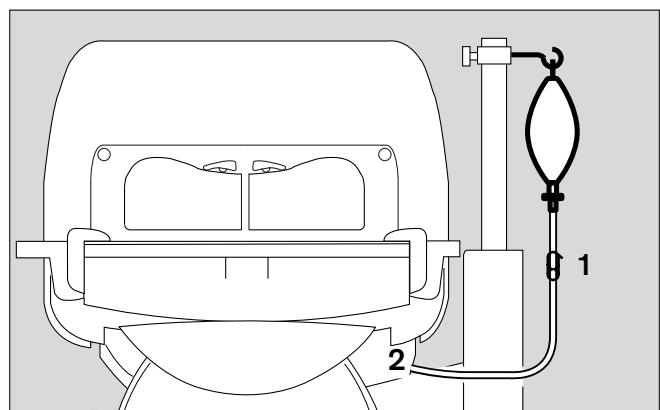
WARNING !

Use only unopened original bags containing pure and sterile distilled water.

Do not use any additives for water intended for humidifying the incubator.

Water bags for humidification must not be confused with infusion solutions!

- Disinfect hands.
- Prepare fresh water transfer set (MX 17 018).
 - 1 Close clamp on water transfer set.
- Insert the pin of the connection tube into the connector of the water bag.
 - 1 Open the clamp on water transfer set.
- Bleed water transfer set (let distilled water drain off).
 - 1 Close clamp on water transfer set.
- 2 Connect the luer lock connection to the water connection pipe.
 - 1 Open the clamp on water transfer set.
- Switch on humidification module on Caleo and adjust humidity setpoint (see page 74).



Replacing the water bag:

An empty water bag will trigger a water supply alarm on Caleo.

- Disinfect hands.
- Close clamp on water transfer set.
- Replace water bag and reopen clamp.

Integrated power strip

The integrated power outlet strip can be used to connect

- infusion pumps and
- SpO2 measuring equipment

as well as other equipment.

WARNING !

Connections to the integrated power strip should only be made by factory trained and authorized technical service personnel.

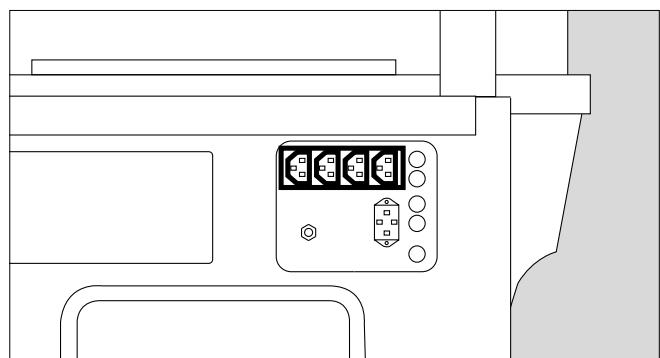
Output of the integrated power strip is not monitored!

Do not connect life support devices which do not have their own power failure alarm.

⚠ Do not exceed the maximum permissible power input for connected accessories

(all 4 sockets together: max. 2A).

Do not exceed the maximum permissible total leakage current. For the leakage current of Caleo without socket strip (see "Technical Data", page 148).



Checking Readiness For Operation

Before Using For the First Time

Before Each Use

Checking Readiness For Operation

Before Using For the First Time

- Check that line voltage corresponds with the specification on the rating plate.
- Check that the elevation above sea level has been entered correctly for the location of the incubator (see page 97).

Before Each Use

- Check that the equipment has been disinfected according to an approved hospital protocol.
- Check that an adequate gas supply is available for all equipment to be used.
- Check that all accessories and auxiliary therapy equipment required are at hand and in proper working condition. Only use components that have been properly processed. Check readiness for operation of auxiliary devices in accordance with their respective Operating Instructions.
- Check that there are no cracks or sharp, chipped edges on the incubator canopy.
- Check that the hinges and catches on the canopy are in proper working order.
- Check that cables and hoses have been routed correctly and safely.
- Check that there is sufficient clearance for adjusting tilt and height of the incubator bassinet.
- Connect to line power supply.
- Check that the openings in the sensor unit are not clogged with dirt.

WARNING !

Do not use a power outlet strip for supplying power to the Caleo incubator!

Connecting the incubator via a power outlet strip may, in case of failure of the protective earth conductor, cause patient leakage currents to rise above permitted limits with a risk of electric shock to the patient.

Before using the unit, make sure that the following tests as well as the checks described under "Before Reusing With a Patient", page 115, have been performed:
Disinfect hands before each test!

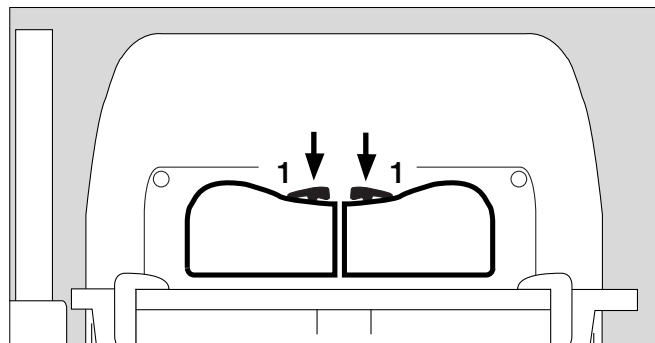
Check that hand ports latch securely

- Perform this test on all 4 hand ports

- 1 Press catch to open hand port.
- Close hand port until latch engages twice.
- Pull edge of hand port – it must not open.

If hand port latches do not remain properly engaged:

- Take unit out of service.



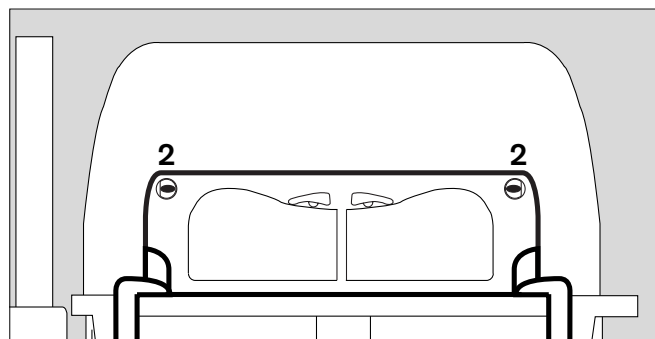
Check that large access doors latch securely

- Perform this test on both doors

- Open door slightly.
- 2 Then, push door back into its closed position. Turn the two knobs outwards until they engage in the horizontal position.

WARNING !

Always ensure that both knobs are engaged in position in order to avoid any risk of an infant falling out of an incubator.
The red catch behind each knob must no longer be visible!



If the front door fails to remain engaged or if the red marking is visible:

- Take unit out of service.

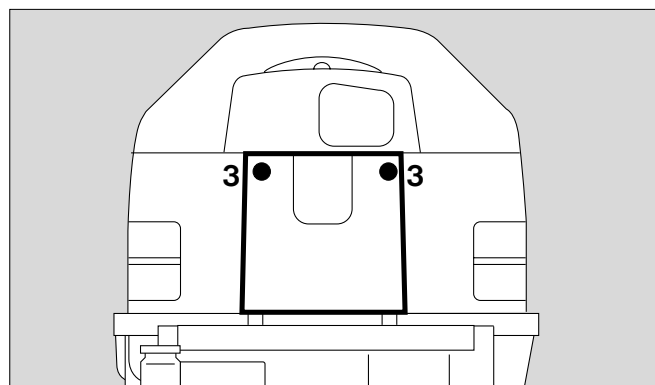
Check that the side door latches securely

- Perform this test on both side doors

- Open side door slightly.
- 3 Then, push door back into its closed position. Turn the two knobs outwards until they tangibly engage in the horizontal position.

WARNING !

Always ensure that both knobs are engaged in position in order to avoid any risk of an infant falling out of an incubator.
The red catch behind each knob must no longer be visible!



If the side door fails to remain engaged or if the red marking is visible:

- Take unit out of service.

Checking Readiness For Operation

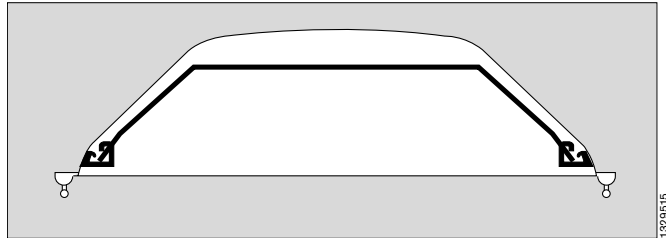
Before Each Use

Check that the double wall is securely in place

- All 4 retaining clamps in the canopy must be seated in the holes of the double wall.

If the double wall or the retaining clamps in the canopy appear damaged:

- Take unit out of service.

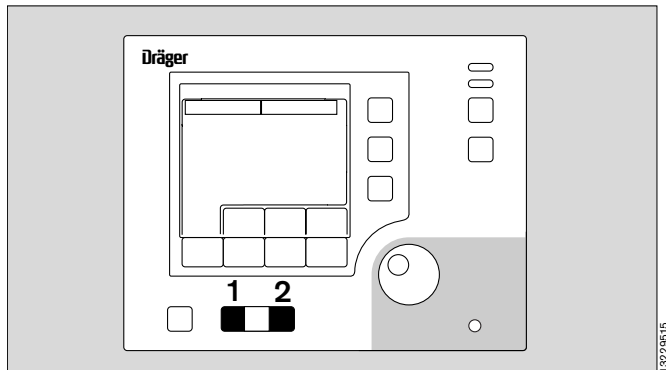


Check the bed tilting mechanism

- 1 Tilt the bed.

During the tilting process, the entire housing of the Caleo must move smoothly. Otherwise:

- Take unit out of service.



WARNING !

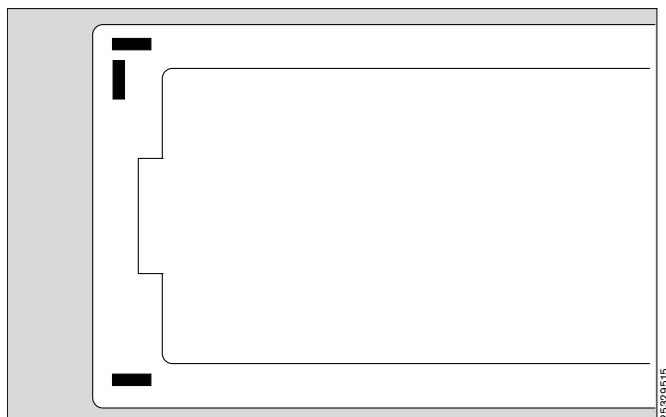
Do not reach between incubator housing and housing support while tilting the bassinet. Risk of injury!

- 2 Return bed to a horizontal position (see page 43).

- The levels in the bed indicate whether the bed is in a horizontal position. This is important when using the integrated infant scale (see page 103).

If the levels are damaged:

- Take unit out of service.

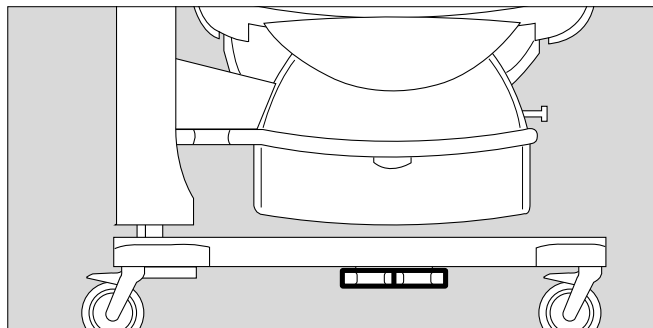


Check the height adjustment mechanism*

- Press both foot pedals in succession to raise and lower Caleo (see page 42).
- After the test, adjust to a comfortable working height.

When adjusting the height, the entire Caleo bassinet must lift up and down smoothly, otherwise:

- Take unit out of service.



Check line power failure alarm

- Disconnect unit from line power.
- 1 The power failure LED should start blinking.

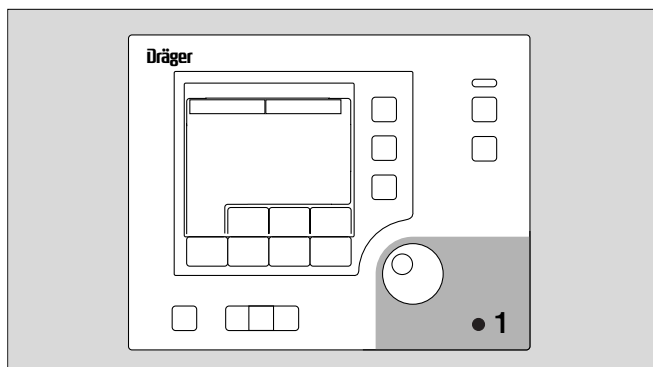
An intermittent audible alarm should start. Its volume must remain constant for at least 30 seconds.

If the volume decreases too soon:

- Leave incubator connected to power and switched on for 24 hours to recharge the NiCd battery of the power failure alarm.
- Repeat check.

If the volume decreases again too soon:

- Take unit out of service.



Start self test, check all displays and sound.

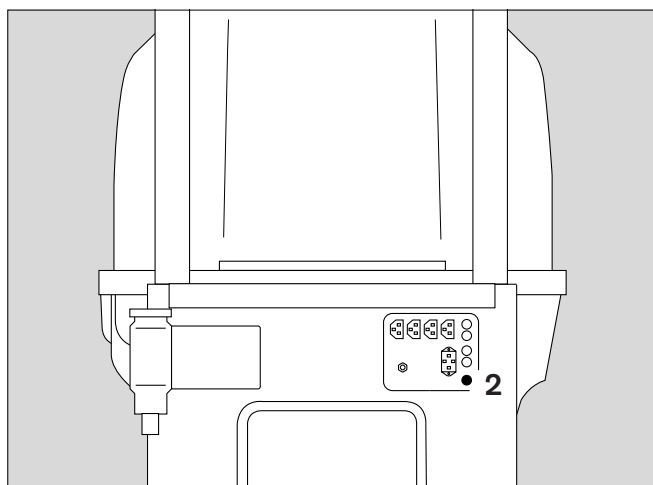
- 2 To switch unit on, press the on/off switch until it engages.
 - The incubator performs a self test.

It is the responsibility of the operator to verify screen displays, LEDs, and audible alarms (enunciator and tone sequence).

- The incubator will sound both an enunciator signal and alarm tone sequence.

If one of the audible alarms does not sound:

- Take unit out of service.



Checking Readiness For Operation

Before Each Use

- Initially, screen and LEDs are dark, then illuminated.

If individual pixels on the screen or LEDs appear to be failing or images are "burnt" into the screen:

- Take unit out of service.

- The opening screen is displayed.

If no opening screen appears on the display:

- Take unit out of service.

The unit is now switched on.



WARNING!

The Caleo incubator is ready for operation only when all checks have been performed successfully.

Operation

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Operation

Precautions During Infant Care

Before each use, check that the unit is ready for operation (see page 46, page 115).

WARNING !

Make sure that all hoses and cables are routed correctly and safely without obstruction! Otherwise:
Risk of extubation! Danger of disconnection!

WARNING !

Never leave infant unattended when the canopy, double walls, front door, or hand ports are open, when the bed has been pulled out or when access grommets have been removed. Risk of patient injury. Infant may fall out of the incubator.

Active infants must be observed with particular care.

WARNING !

Always observe the maximum load of the patient bed (5 kg, 11 lbs).
Do not lean on or apply weight to the bed when it has been pulled out.

Do not use the x-ray drawer as writing support or bed for the infant.

Always allow sufficient time for incubator to warm up to the required temperature before use (see page 149).

WARNING !

Avoid additional external heat sources, such as direct sunlight, spot lamps, and electric pads or blankets. They cause the air temperature inside the incubator to increase in an uncontrolled fashion.

WARNING !

The infant's central temperature must be regularly monitored with an independent thermometer.

WARNING !

It is the responsibility of the attending physicians to draw conclusions from the measured skin temperature.

WARNING !

Do not use skin temperature control mode for infants in shock, as their skin temperature is much lower than normal. Skin temperature control would increase the incubator air temperature too much, resulting in the risk of overheating the infant.
We recommend operating the Caleo incubator in air temperature control mode when caring for patients with such conditions – see page 57.

WARNING !

Do not use skin temperature control mode for infants with a fever, since their skin temperature is much higher than normal. Using skin temperature control would reduce the incubator air temperature too much, resulting in the risk of hypothermia.

WARNING !

Skin temperature control mode must not be used on twins, since Caleo controls only the temperature for one infant. Risk of hypothermia or overheating. Always use air temperature control mode when caring for twins.

WARNING !

Do not confuse skin sensor probe positions on the infant's body! The yellow skin temperature sensor (T1) is used for skin temperature control. Inappropriate positioning of this sensor could lead to overheating of the infant.

WARNING !

Do not place any blankets or sheets over the hot air vent. The temperature control system would be disrupted, causing a risk of overheating or burn if air from the hot air vent is channelled directly to the infant.

WARNING!

Cleaning mode may only be used while Caleo is not occupied by a patient.
After use, allow Caleo to cool down before dismantling.
Risk of burns when touching the heater!

WARNING !

During a power failure, the lack of fresh air supply may cause an elevated CO₂ concentration inside the patient capsule. Risk of CO₂ poisoning.

The central alarm LED may be disabled in the system configuration. Always check alarm LEDs on control unit.

When treating larger babies, their higher caloric output may cause the air temperature in the Caleo incubator to rise. In this case, the double wall should be removed.

WARNING !

Beware of cross-infections when treating twins!

NOTE: For proper temperature control of the incubator, room temperature must be at least 3 °C lower than the air temperature set for the incubator.

Oxygen therapy**WARNING !**

Fire hazards from oxygen !

- No open flames or cigarettes ! Textiles, plastics, and oils readily ignite in an oxygen enriched atmosphere and burn with great intensity.
- Keep oxygen valves, connections, and seals free from oil and grease.
- Open valves on O₂ cylinders slowly.
- Do not operate Caleo in the presence of flammable anesthetics or disinfectants. Risk of explosion!
- Do not use or store flammable liquids such as alcohol, ether, or acetone inside the Caleo incubator.
- Do not use electrical equipment inside the patient capsule unless this equipment is expressly designed for use in environments that present an explosion hazard.

WARNING !

Due to the physiological risks from O₂, it is mandatory to monitor O₂ concentrations continuously during the administration of O₂, either using the integrated O₂ measurement and control system or an independent O₂ analyzer.

WARNING !

Always take into consideration the physiological risks from the administration of oxygen.
Elevated oxygen concentrations inside the incubator may only be used by or on the order of a physician.
It is absolutely essential that such oxygen therapy be selected and controlled on the basis of the arterially measured oxygen partial pressure in the infant's blood.
This is the only way to minimize the risk of both hyperoxemia (with potential for damage to the eyes by retrolental fibroplasia) and hypoxemia (which might contribute to intraventricular hemorrhage and damage to the infant's brain).

WARNING !

Medicated aerosols and similar substances must not be nebulized in the infant capsule.
The mist of nebulized substances may impair the proper function of the incubator.

CAUTION!

Never cover the sensor unit or hang anything from the slits in the sensor unit. Keep slits in the sensor unit free from dirt.

Doors

When closing the doors, make sure that the patient is not lying in the closing path.

The doors are not properly shut until the red catches behind the knobs are no longer visible!

When opening and closing the doors, make sure that the hoses and cables are not caught in the moving double wall!

Side doors

When opening and closing the side flaps, make sure that the hoses and cables are routed safely and clear of any obstructions. The side flaps are only properly shut when the red catches behind the release knobs are no longer visible.

Canopy

The canopy must not be used as a shelf for placing clothing, instruments etc..

Before moving the canopy, make sure that nothing has been laid on top of it.

When fitting and removing the incubator hood canopy, hold it firmly in your hand.

The canopy installation catch must engage correctly.

Do not try to lift the canopy when catch is engaged.

Do not tilt the canopy forwards.

When closed, make sure that the canopy sits firmly in place!

Double wall

Always remove the canopy from Caleo first, before installing or removing the double wall.

Kangaroo Mode

WARNING !

When using Kangaroo Mode, central temperature of the infant, who is outside the controlled climate of the incubator, must be monitored constantly. Particular attention must be paid to critical care patients' vital parameters, especially a critical O₂ partial pressure. Ensure that all cables and hoses are routed correctly and safely.

When using phototherapy

WARNING !

Infant temperature must be monitored with particular care during phototherapy. Absorption of light through the infant's skin will supply heat to the patient which may increase central temperature.

For this reason:

- Decrease temperature setting for incubator air by approximately 2 °C at least 15 minutes before starting phototherapy.
- Lower humidity setpoint.
- Room temperature must be at least 3 °C lower than the Caleo air temperature. This value applies for Dräger Model 4000 phototherapy units.
- The temperature of the incubator air may rise even more noticeably when using other phototherapy units, especially units without built-in fan.

CAUTION !

Only use phototherapy units supplied with their own stand. Do not put phototherapy devices directly on Caleo canopy.

WARNING !

During phototherapy, the supply of fluids to the infant must be increased, e.g. by parenteral infusion, to compensate for the increased water loss.

WARNING !

Never cover phototherapy lamp or incubator canopy with cloths, aluminium foil or other materials with the intention to boost the phototherapeutic effect. A heat build-up will likely result with the danger of overheating the infant, because the incubator cannot be adequately cooled with ambient air under these conditions.

WARNING !

Always use eye protection for the infant when using phototherapy.

Tilting/height adjustment

WARNING !

Ensure that the ventilator circuit and all other cables, hoses and tubing are routed correctly and safely.
Danger of extubation and disconnection!
 Hoses and/or cables are at risk of being trapped when tilting the Caleo, adjusting the height, and when opening and closing the front door.

In-house transport

CAUTION !

Use caution when moving the incubator over uneven surfaces, e.g. rough pavement outside the hospital or into an elevator, as castors may become damaged or dislodged.

High noise levels

Excessive noise levels that can disturb the patient may be caused by:

- using O₂ head boxes and delivering pressurized gases,
 - wear on the bearings of the fan motor,
 - placing objects on the canopy.
- Observe the specified maintenance intervals – see page 121.

Electrical safety

WARNING !

Caleo is to be used only in rooms with line power installations that comply with national safety standards for hospital patient rooms (e.g., IEC/EN 601.1, "Safety of Medical Equipment").
To maintain grounding integrity, connect only to a "hospital grade" receptacle.
Always disconnect supply before servicing.

WARNING !

Do not use a power outlet strip for supplying power to the Caleo incubator!
 Connecting the incubator via a power outlet strip may, in case of failure of the protective earth conductor, cause patient leakage currents to rise above permitted limits with a risk of electric shock to the patient.

WARNING !

Only use auxiliary electromedical equipment which complies with national safety standards for hospital patient rooms (e.g., IEC/EN 601.1, "Safety of Medical Equipment", UL 544).
When using the integrated power strip to connect auxiliary devices, always observe total leakage current and current consumption limits!
 (See "Technical Data", page 148.)

WARNING !

The output of the integrated power strip is not monitored!
Do not connect life support devices which do not have their own power failure alarm.

WARNING !

Mobile telephones must not be used within 10 meters (33 feet) of the incubator. Mobile telephones can interfere with the functioning of electromedical equipment and therefore endanger the patient.*

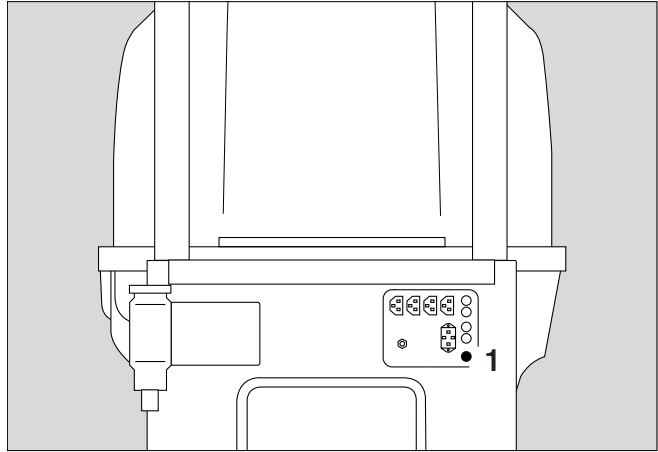
* Dräger medical equipment conforms to the interference immunity requirements laid down in product-specific standards or in EN 60601-1-2 (IEC 60601-1-2). However, depending on the design of a mobile phone and the use situation, field strengths exceeding the values laid down in the specified standards may be generated in the immediate vicinity of mobile phones, thereby causing interference and malfunctions.

Operation

Switching Caleo On

Switching Caleo On

- Connect unit to line power.
- 1 To switch unit on, press the on/off switch until it engages.



An audible alarm is emitted.

- The opening screen is displayed.

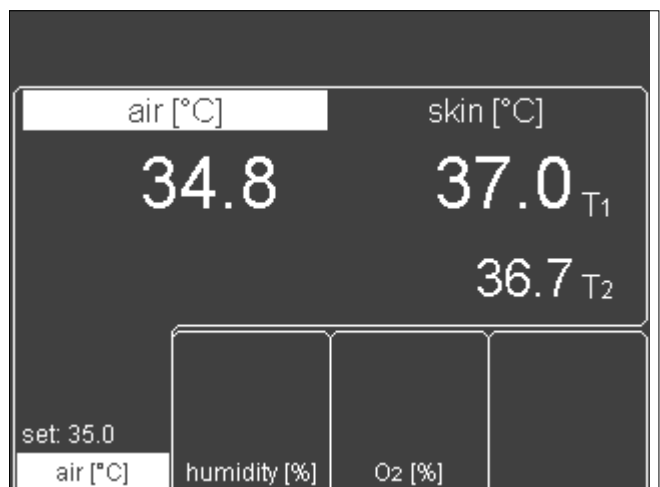
The incubator performs a self-test.

It is the responsibility of the operator to verify screen displays, LEDs, and audible alarm (see page 49).



- After the self-test, the standard screen for air temperature control is displayed.
- The currently activated function is always highlighted by a light background.

NOTE: In air temperature control mode, the unit takes 20 minutes to warm up. During this period, the alarm for "Air temp. deviation above 1.5 °C" is suppressed.



Using Air Temperature Control

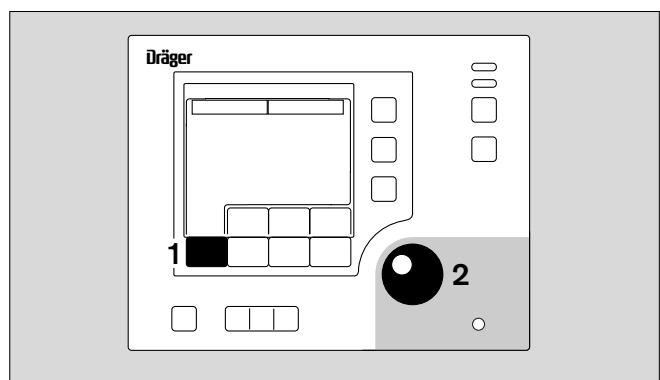
WARNING !

Regularly measure infant temperature!
Do not leave canopy open for any length of time,
otherwise the air temperature inside the incubator will drop.

Adjusting air temperature setpoint


Standard setpoint range	28 °C to 37 °C
Extended setpoint range	37.1 °C to 39 °C
	20 °C to 27.9 °C
Default setpoint	33 °C

- 1 To adjust setpoint, press key.



- The current (measured) value and setpoint appear on screen both as bar graphs and numerical values.
 - The message »set value with rotary knob« appears at the top of the screen.
- 2 Turn rotary knob clockwise to increase setpoint.
 - 2 Turn rotary knob counterclockwise to decrease setpoint.
 - 2 Press rotary knob to confirm new setting.

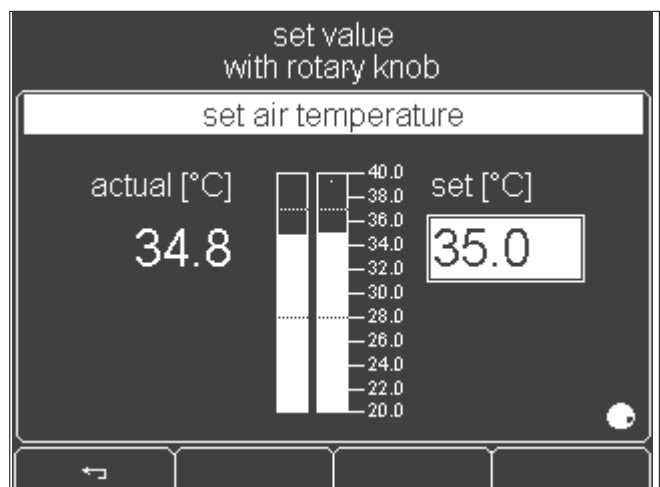
If you do not wish to change the settings:

Press  and the new settings will be cancelled

The display returns to the standard screen. The previous setpoint is retained.

Or

- Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. If the rotary knob is not pressed, the display will automatically return to the standard screen after 7 seconds, and the previous setpoint will be retained.



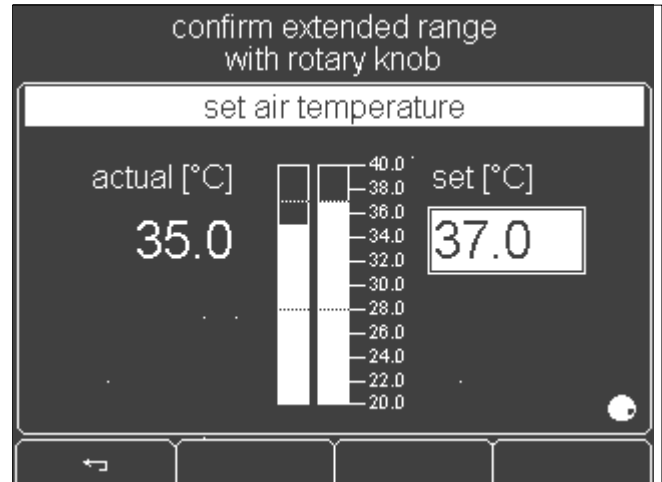
Using the extended air temperature setpoint range


If the standard setpoint range is exceeded:

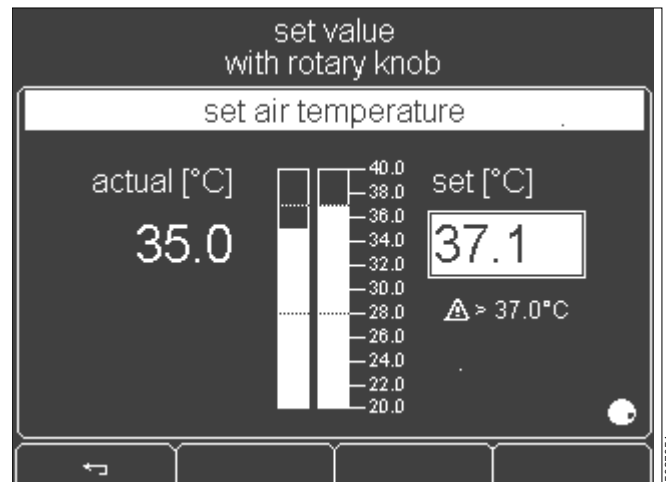
- The advisory message
»confirm extended range with rotary knob«
will appear at the top of the screen.
- Press rotary knob to activate extended range.
- Turn rotary knob clockwise to increase setpoint further.

WARNING !

When the extended setpoint range for air temperature is used, particular care must be taken to monitor infant temperature.

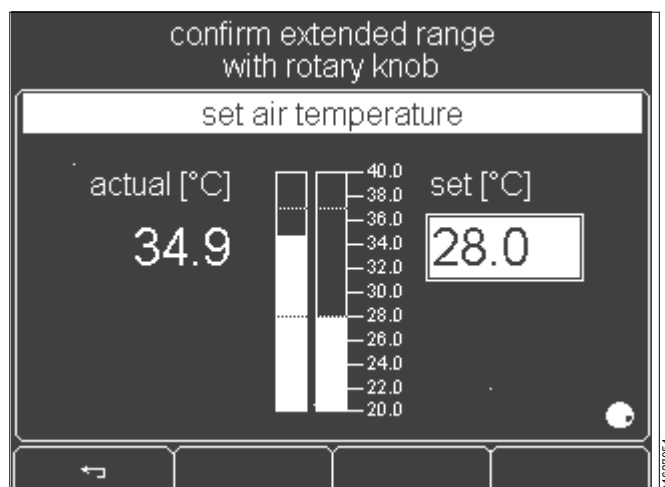


- The advisory message » >37.0 °C« appears on screen.
- The following message appears at the top of the screen:
»set value with rotary knob«
- Press rotary knob to confirm the new setpoint.

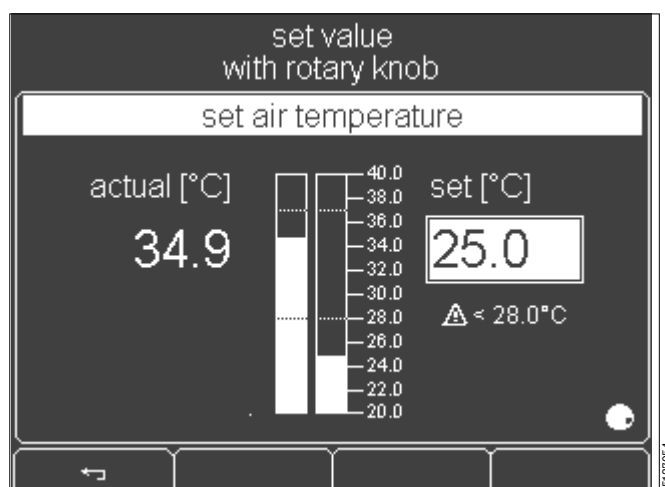


If the specified setpoint is below the standard setpoint range:

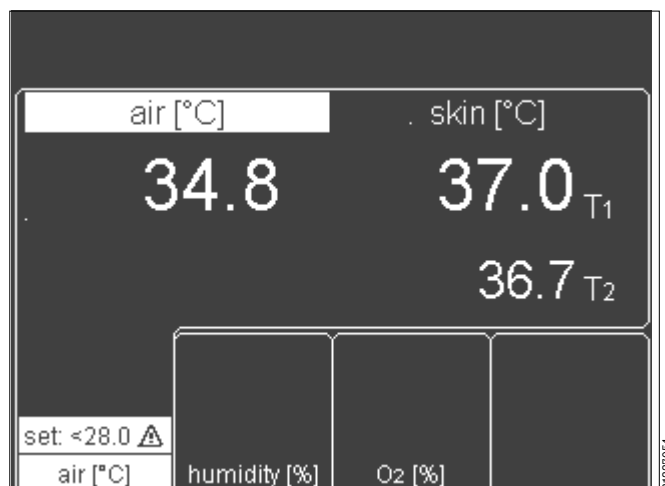
- The advisory message
»confirm extended range with rotary knob«
appears on screen.
- Press rotary knob to activate extended range.
- Turn rotary knob counterclockwise to decrease set value further.



- The advisory message » $\Delta < 28.0^{\circ}\text{C}$ « appears on screen.
- The following message appears at the top of the screen
»set value with rotary knob«.
- Press rotary knob to confirm new setpoint.



- The display returns to the standard screen. The measured values are displayed.
- The set value and »set: $< 28.0 \Delta$ « are displayed alternately.



Operation

Using Air Temperature Control

Reducing air temperature inside the incubator

The cooling rate is determined by the incubator design and can be increased by

- removing the double walls,
- reducing the outside temperature (if possible),
- reducing the humidity setpoint, and
- partially or completely removing incubator canopy if used.

NOTE: Cooling is not accelerated by reducing the required air temperature below the value actually intended.

In case of an **urgent** need for cooling:

Open canopy, large access doors, side doors, or hand ports.

WARNING !

Monitor infant constantly when canopy, doors, or hand ports are open, to ensure infant cannot fall out of the incubator.

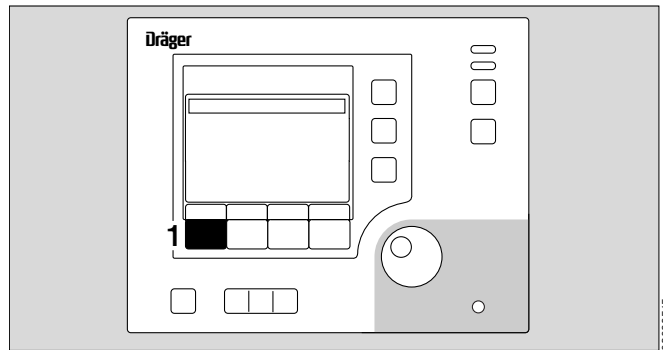
If you do not wish to activate the new setpoint:

- 1 Press button to cancel adjustment of the new setpoint.

The screen returns to the standard display mode and the former setpoint is retained.

Or

- Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. If the rotary knob is not pressed, the display will automatically return to the standard screen after 7 seconds, and the previous setpoint will be retained.

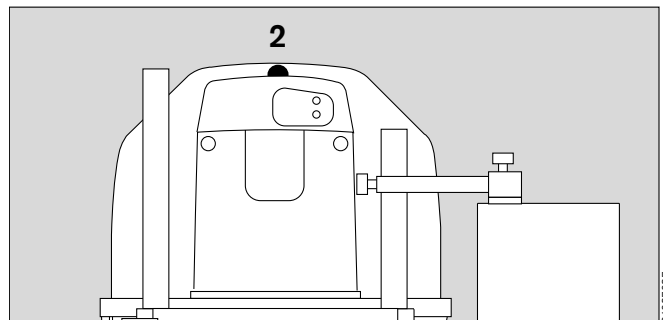


Alarms

Alarm limits can be changed in the configuration (see page 98).

If the deviation between set and measured air temperature values exceeds 1.5°C^* :

- On screen, a warning message appears:
»Air temp. deviation above 1.5°C «
 - an intermittent audible alarm (3 beeps) sounds
- 2 The central alarm indicator lights up**.



* The numerical values in this description are examples, see "Configuring alarm settings", page 98.

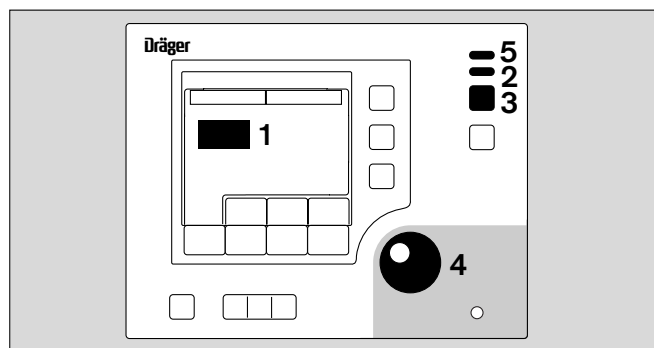
** If not disabled in the configuration system settings, page 97

- 1 The measured value starts flashing.
- 2 The yellow alarm LED starts blinking.

The intermittent audible alarm can be silenced for 15 minutes.

- 3 To silence audible alarm, press key,
- or
- 4 press rotary knob.

- The warning message remains on the screen,
- The intermittent alarm tone is muted,
- The central alarm indicator goes out,
- 1 The measured value continues to flash,
- 2 The yellow alarm LED continues to flash.



When the measured value returns within the range ± 1.5 °C:

- The warning message disappears.
- The intermittent alarm tone is muted.
- The central alarm light goes out,
- 1 The measured value remains on-screen, without flashing.
- 2 The yellow alarm LED goes out.

In case air temperature is over 38 °C (or over 40 °C when using the extended setpoint range):

- The screen displays the warning message:
»Air temperature too high«,
- An intermittent audible alarm sequence (5 beeps) sounds,
- The central alarm light is lit*,
- 1 The measured value starts flashing,
- 5 The red alarm LED starts blinking.

The audible alarm can be silenced for 5 minutes.

Caleo heats up if necessary to reach the specified interior air temperature setting.

- 1 The measured value continues to flash,
- 5 The red alarm LED continues to flash.

When the air temperature drops below the alarm threshold:

- 3 Press key and the alarm is cancelled.

For other alarms, see "Troubleshooting", page 124.

See also "Alarm Description", page 143.

* If not disabled in the configuration system settings, page 97

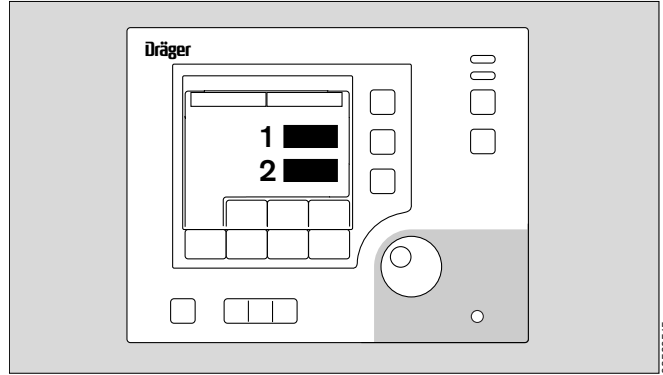
Using Skin Temperature Measurement

Checking proper function of the temperature sensors

Immediately before using the yellow skin temperature sensor or the white peripheral sensor, insert it into the yellow or white socket, respectively, and wait for a measurement signal to appear on screen.

- 1 Measurement signal from the yellow skin temperature sensor (T1)
- 2 Measurement signal from the white peripheral temperature sensor (T2)

If no measurement signal appears, the respective sensor must be replaced (page 127).



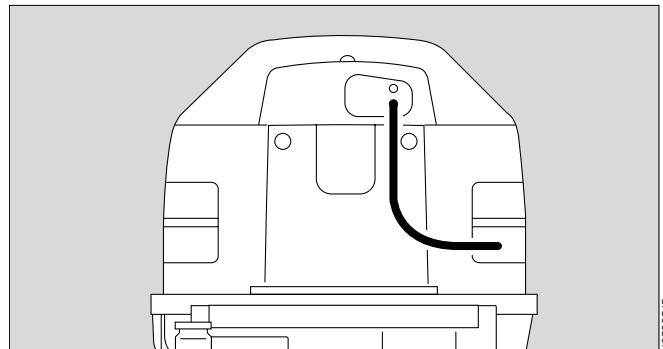
WARNING !

Always verify that skin temperature sensor probe is specified and approved for use with Dräger Caleo.

Using skin temperature measurement in air or skin temperature control modes.

Connect the temperature sensors for measuring skin and peripheral temperature:

- Plug **yellow** skin temperature connector into **yellow** socket on the sensor unit (T1, skin or "tummy" temperature).
NOTE: When using skin temperature control mode, the servo control is performed with reference to this sensor.
- Plug connector of the white peripheral temperature sensor into the white socket on the sensor unit (T2, peripheral or "toe" temperature, or when using air temperature control mode for twins, the skin temperature of the second infant).
- Route sensor cable through one of the flexible U-grommets.
- Remove protective foil from the adhesive pad and place skin temperature sensor on the pad.
- Using the adhesive pad, attach sensor tip to the appropriate part of the infant's skin.



Positioning the skin temperature sensor (yellow):

If the infant is lying on his/her back:

- Attach the yellow sensor to the abdomen, near the liver.

If the infant is lying on his/her belly:

- Attach the yellow sensor to the back, preferably near the kidneys.

Positioning the peripheral temperature sensor (white):

- Attach the white sensor to the extremities, preferably the foot or arm.

WARNING !

Do not use skin temperature sensors to measure rectal (central) temperature!

Do not locate sensor under the infant, otherwise measurement and control would be performed with reference to infant central temperature instead of skin temperature.

WARNING !

Regularly check that skin temperature sensor is properly attached to the infant's skin! A skin temperature probe that has fallen off would be measuring air temperature with a risk of overheating the infant (although the air temperature would not rise above 39 °C).

NOTE: When a skin temperature sensor is attached, measured skin temperature is displayed even when "air temperature control" is the active mode. However, incubator temperature is not controlled as a function of skin temperature in this case.

Switching Between Air and Skin Temperature Control

WARNING !

Do not use skin temperature control mode for infants in shock, as their skin temperature is much lower than normal. Skin temperature control would increase the incubator air temperature too much, resulting in the risk of overheating the infant.

We recommend operating the Caleo incubator in air temperature control mode when caring for patients with such conditions – see page 57.

WARNING !

Do not use skin temperature control mode for infants with a fever, since their skin temperature is much higher than normal. Using skin temperature control would reduce the incubator air temperature too much, resulting in the risk of hypothermia.

WARNING !

Skin temperature control mode must not be used on twins, since Caleo controls only the temperature for one infant. Risk of hypothermia or overheating. Always use air temperature control mode when caring for twins.

WARNING !

Do not confuse skin sensor probe positions on the infant's body! The yellow skin temperature sensor (T1) is used for skin temperature control. Inappropriate positioning of this sensor could lead to overheating of the infant.

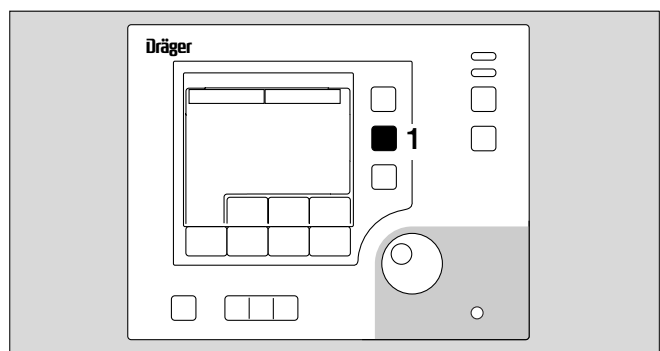
WARNING !

Regularly measure infant temperature!
Do not leave canopy open for any length of time, otherwise the air temperature inside the incubator will drop.

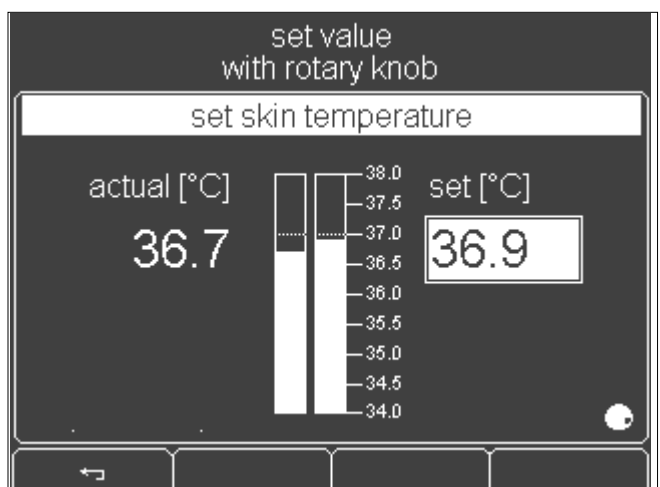
WARNING !

Regularly check that skin temperature sensor is properly attached to the infant's skin! A skin temperature probe that has fallen off would be measuring air temperature with a risk of overheating the infant (although the air temperature would not rise above 39 °C).

- 1 Press key to change temperature control mode.
- 1 The LED for the control mode will start blinking, thereby requesting confirmation of the mode change.



- The activated control mode is displayed on screen. Actual, measured value, and setpoint are displayed as bar graphs and numeric values.
- The upper part of the screen displays the message: »set value with rotary knob«.

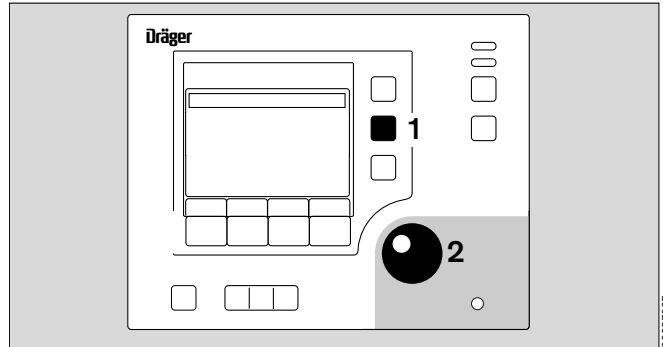


Operation

Switching Between Air and Skin Temperature Control

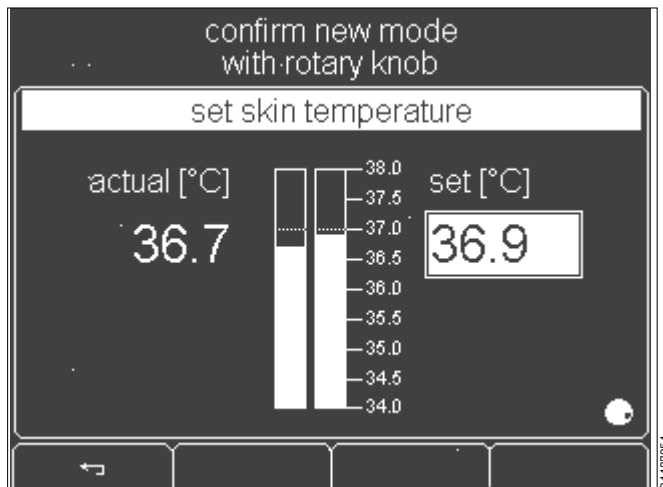
After the new mode has been activated, you can set the desired value with the rotary knob.

- 1 The LED of the activated mode will start blinking.
- 2 Turn rotary knob to adjust setpoint.
- 2 Press rotary knob to confirm the new setpoint.



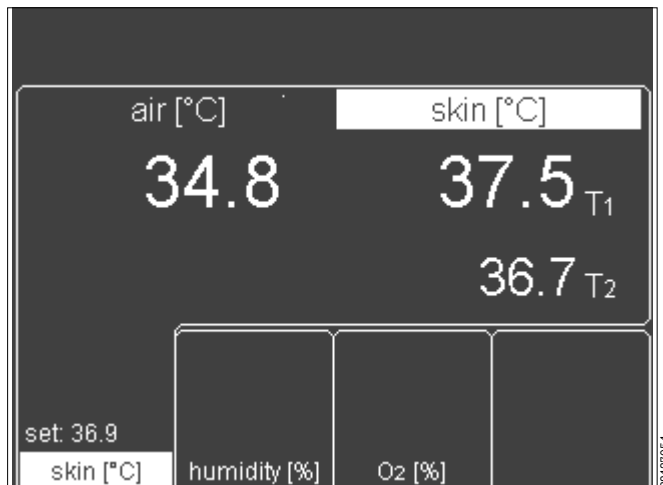
- The upper part of the screen displays the advisory message:
»confirm new mode with rotary knob«.

- 2 Press rotary knob to confirm the new mode.




The display returns to the standard screen.

- 1 The LED of the activated mode is now continuously lit.



If you do not wish to change the settings:

- Press  and the new settings will be cancelled. The display returns to the standard screen. The previous setpoint is retained.

Or

- Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. If the rotary knob is not pressed, the display will automatically return to the standard screen after 7 seconds, and the previous setpoint will be retained.

Using Skin Temperature Control

WARNING !

Do not use skin temperature control mode for infants in shock, as their skin temperature is much lower than normal. Skin temperature control would increase the incubator air temperature too much, resulting in the risk of overheating the infant.

We recommend operating the Caleo incubator in air temperature control mode when caring for patients with such conditions – see page 57.

WARNING !

Do not use skin temperature control mode for infants with a fever, since their skin temperature is much higher than normal. Using skin temperature control would reduce the incubator air temperature too much, resulting in the risk of hypothermia.

WARNING !

Skin temperature control mode must not be used on twins, since Caleo controls only the temperature for one infant. Risk of hypothermia or overheating. Always use air temperature control mode when caring for twins.

WARNING !

Do not confuse skin sensor probe positions on the infant's body! The yellow skin temperature sensor (T1) is used for skin temperature control. Inappropriate positioning of this sensor could lead to overheating of the infant.

WARNING !

Regularly measure infant temperature!
Do not leave canopy open for any length of time, otherwise the air temperature inside the incubator will drop.

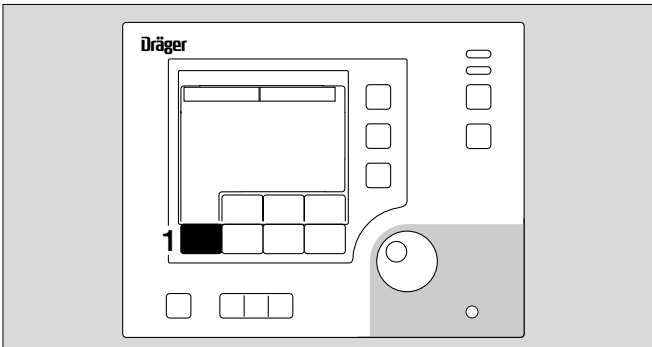
WARNING !

Regularly check that skin temperature sensor is properly attached to the infant's skin! A skin temperature probe that has fallen off would be measuring air temperature with a risk of overheating the infant (although the air temperature would not rise above 39 °C).

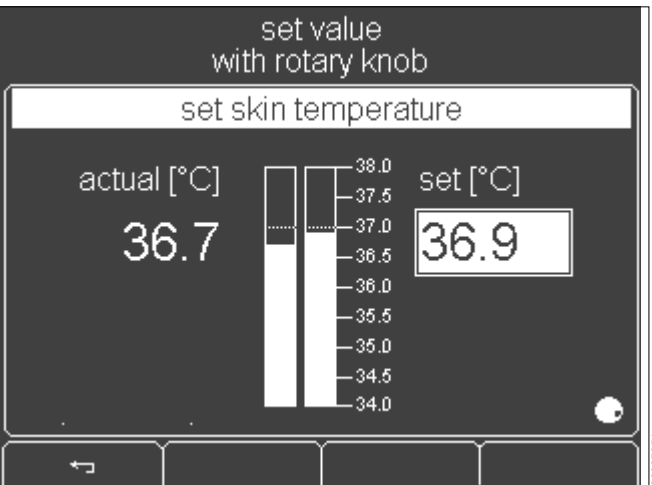
Adjusting the setpoint

Standard setpoint range	34 °C to 37 °C
Extended setpoint range	37.1 °C to 38 °C
Default setting	36.5 °C

- 1 Press key to adjust setpoint.




- The actual measured value and setpoint are displayed on screen both as bar graphs and as numerical values.
- The following message is displayed in the top part of the screen:
»set value with rotary knob«.



- 1 Turn rotary knob clockwise to increase setpoint.
- 1 Turn rotary knob counterclockwise to decrease setpoint.
- 1 Press rotary knob to confirm the new setting.

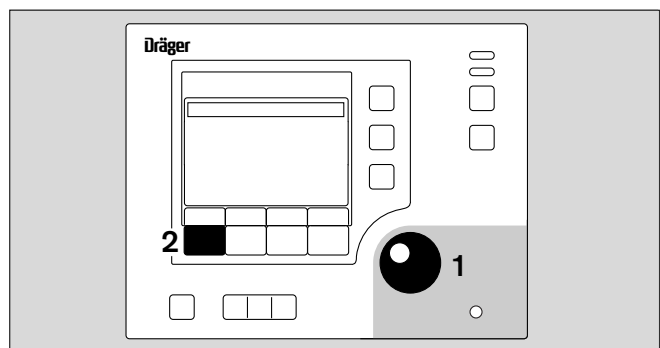
If you do not wish to change the settings:

- 2 Press  and the new settings will be cancelled.

The display returns to the standard screen. The previous setpoint is retained.

Or

- Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. If the rotary knob is not pressed, the display will automatically return to the standard screen after 7 seconds, and the previous setpoint will be retained.



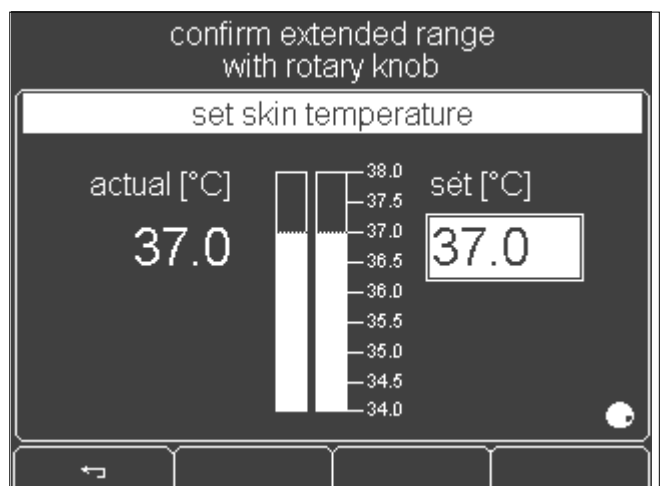
Using the extended setpoint range for skin temperature control


If the standard setpoint range is exceeded:

- The advisory message »confirm extended range with rotary knob« will appear on screen.
- 1 Press rotary knob to activate extended range.
- 1 Turn rotary knob clockwise to increase setpoint further.

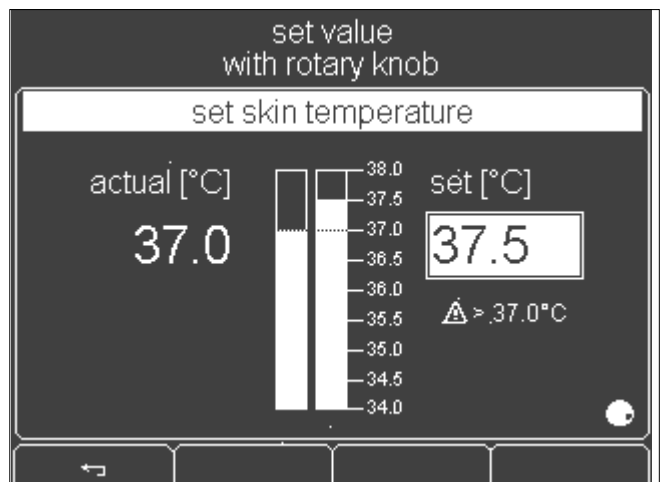
WARNING !

When the extended setpoint range for skin temperature is used, particular care must be taken to monitor infant temperature.




- The advisory message » > 37.0°C« appears on screen.
- The following message appears at the top of the screen: »set value with rotary knob«.

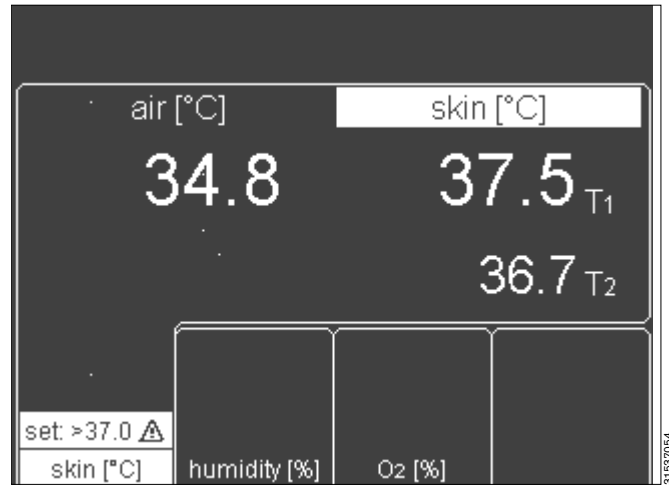
- 1 Press rotary knob to confirm the new setpoint.



Operation

Using Skin Temperature Control

- The display returns to the standard screen. The measured values are displayed.
- The setpoint and » set: > 37.0  « are displayed alternately.



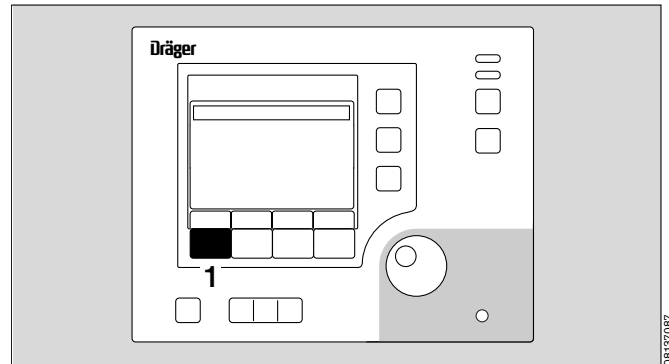
If you do not wish to activate the new setpoint:

- 1 Press button to cancel adjustment of the new setpoint.

The screen returns to the standard display mode and the previous setpoint is retained.

Or

- Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. If the rotary knob is not pressed, the display will automatically return to the standard screen after 7 seconds, and the previous setpoint will be retained.



Alarms

Alarm limits can be changed in the configuration (see page 98).

Example: if the deviation between the set and measured skin temperature exceeds $\pm 0.5^{\circ}\text{C}$:

- The screen displays the warning message
»Skin 1 temp. deviation above 0.5°C «,
 - An intermittent alarm tone sequence (3 beeps) will sound.
- 1 The central alarm light will light up**,
 - 2 The measured value will start flashing,
 - 3 The yellow alarm LED will start blinking.

The intermittent alarm tone sequence can be silenced for 5 minutes:

- 4 Press key to silence intermittent alarm tone,
- or
- 5 Press rotary knob.
- The warning message remains on the screen,
 - The intermittent alarm tone is now silenced.
- 1 The central alarm indicator light goes out.
 - 2 The measured value continues to flash.
 - 3 The yellow alarm LED continues to blink.

When the measured value returns within the range $\pm 0.5^{\circ}\text{C}$:

- The warning message disappears.
 - The intermittent audible alarm is cancelled.
- 1 The central alarm indicator light goes out.
 - 2 The measured value remains on screen without flashing,
 - 3 The yellow alarm LED goes out.

If the sensor plug is disconnected:

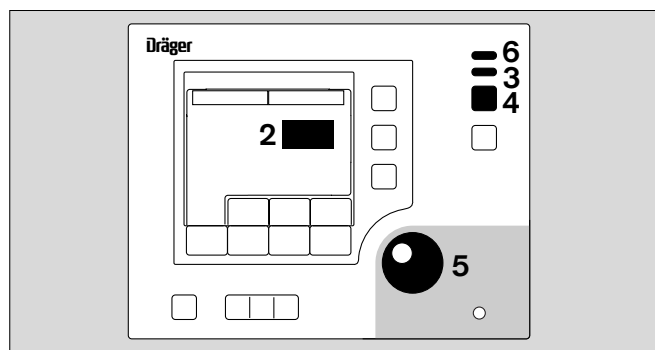
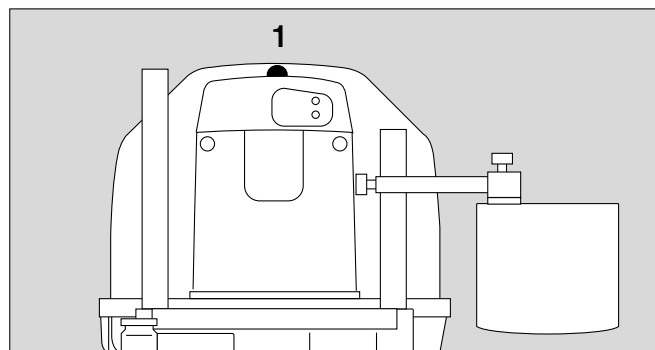
- 3 dashes are displayed instead of the measured value.
- After 3 seconds:
- The screen displays the warning message
»Connect skin 1 sensor«.
 - An intermittent alarm tone sequence (5 beeps) is sounded,
- 1 The central alarm indicator lights up**,
 - 2 The measured value starts flashing,
 - 6 The red alarm LED starts blinking.

In this case:

- Immediately plug in the sensor.

If the sensor is defective:

- The screen displays the warning message
»Skin 1 sensor fault«.
 - The intermittent alarm tone sequence (5 beeps) is sounded,
- 1 The central alarm indicator lights up**,
 - 2 The measured value starts flashing,
 - 6 The red alarm LED starts blinking.



* The *numerical values* in this description are examples.
See "Configuring alarm settings", page 98.

** If not disabled in the configuration system settings, page 97

Operation

Using Skin Temperature Control

Then:

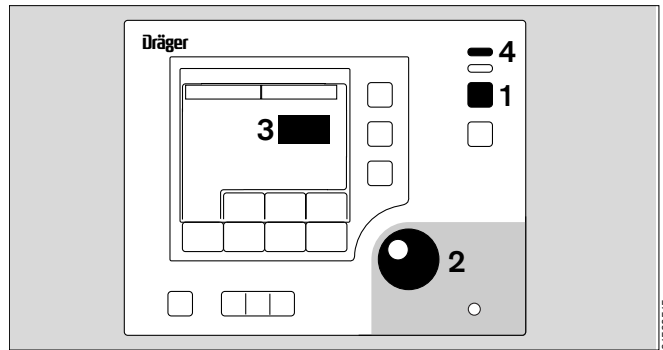
- Replace skin temperature sensor.

WARNING !

As long as 3 dashes remain on screen while the incubator is operated in skin temperature control mode, Caleo will not heat. Infant may become hypothermic.

The alarm tone can be silenced for 5 minutes:

- 1 Press key to silence intermittent audible alarm,
or
- 2 press rotary knob.
 - The warning message remains on the screen,
 - The intermittent alarm tone is silenced,
 - The central alarm indicator light goes out,
- 3 The measured value continues to flash,
- 4 The red alarm LED continues to flash.



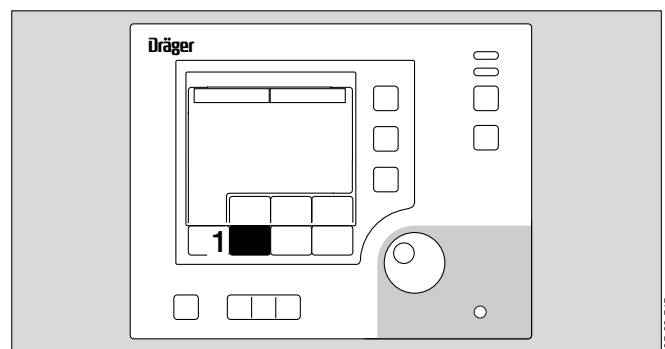
For other alarms, see "Troubleshooting – Error Messages", page 124.

See also "Alarm Description", page 143.

Using Humidity Control*

- Connect the humidifier system (see "Using Humidification Systems", page 44).

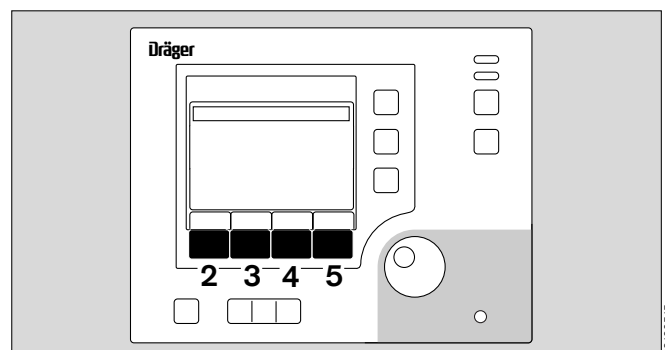
1 Press key to set humidity control.



The actual value and current setpoint of the humidity control are displayed as bar graphs and numerical values.

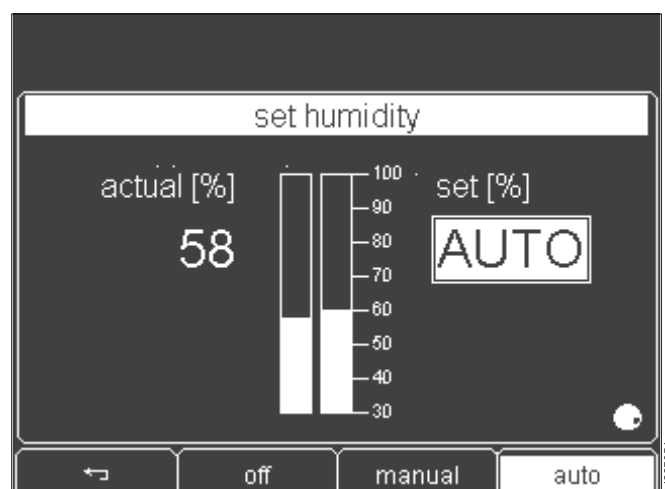
Soft key symbols:

- 2 = New setpoint has not been activated.
- 3 off = Humidity OFF
- 4 manual = Set target value manually.
- 5 auto = Set target value automatically (see page 141).



NOTE: Humidity inside the incubator is servo-controlled both when manually setting a target value and when using AUTO humidity.

- On activating humidity control, AUTO mode is proposed as default.



* Available option

Operation

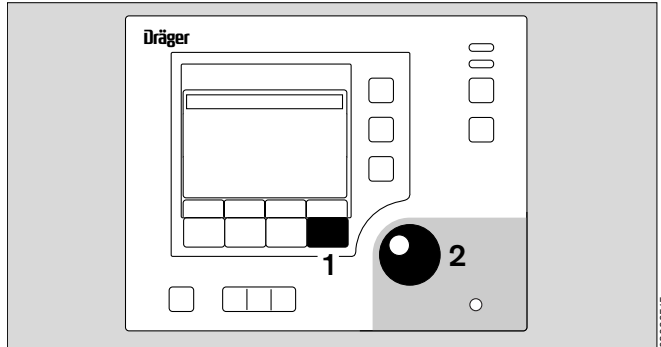
Using Humidity Control

Setting AUTO humidity

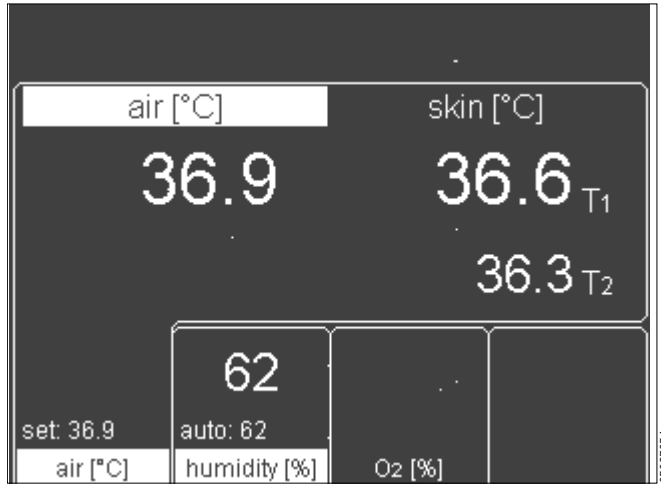
In AUTO mode, the humidity setpoint is automatically calculated and set by the system as a function of the air temperature setting (see page 141).

The maximum relative humidity depends on the ambient temperature and incubator air temperature at max. 75 % relative humidity.

- 1 Press soft key to switch humidity control to AUTO mode.
- 2 Press rotary knob to activate AUTO humidity.



- The display returns to the standard screen. The measured value and the automatic setpoint are displayed.

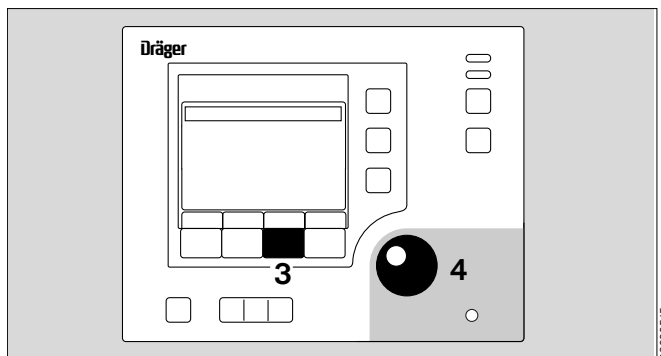


Manually adjusting the setpoint

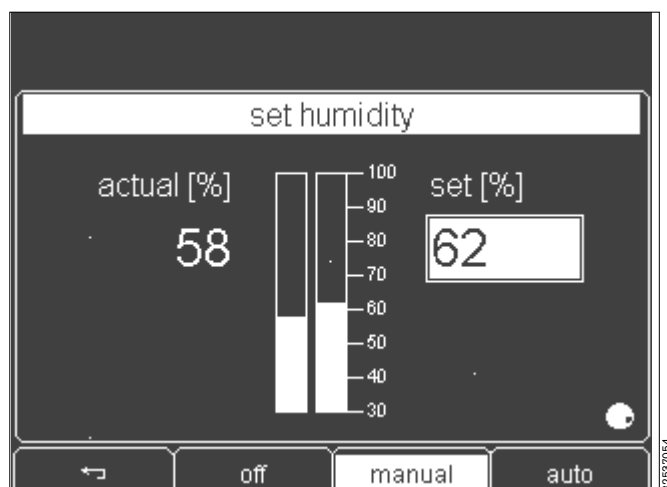
Standard setpoint range 30 % to 99 %
Default value 50 %

- 3 Press soft key to switch humidity control to manual mode.
- 4 Turn rotary knob clockwise to increase setpoint.
- 4 Turn rotary knob counterclockwise to decrease setpoint.
- 4 Press rotary knob to confirm setpoint.

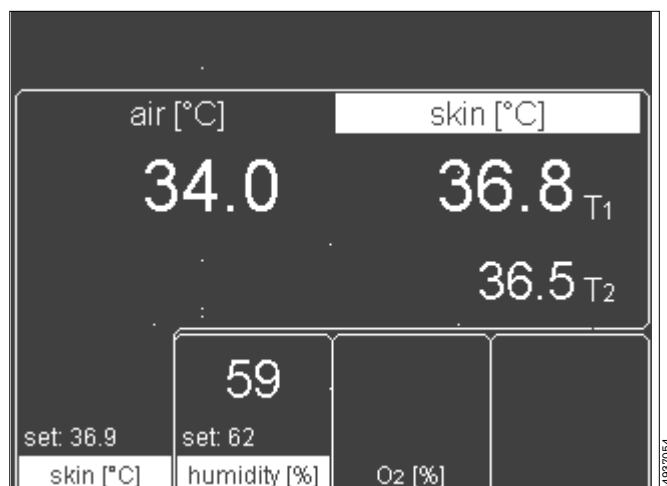
The maximum relative humidity reached is between 85 % and 99 % r.h., depending on the ambient temperature and the incubator air temperature.



- Current measured value and setpoint for controlling humidity are displayed as bar graphs and numerical values.



- The display returns to the standard screen. Measured values and setpoints are displayed.



Alarms

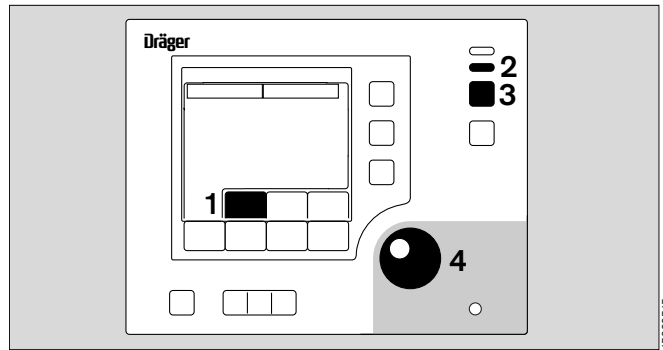
In the event of an empty water supply

- A message
»Water empty, please refill«
appears on screen.
- An alarm tone sequence (3 beeps) starts,
- The central alarm indicator lights up*,
 - 1 The measured value starts flashing,
 - 2 The yellow alarm LED starts blinking.

Fill water reservoir or replace water bag – see page 44 and the subsequent pages.

The intermittent alarm tone sequence can be silenced for 15 minutes:

- 3 Press key to silence intermittent alarm tone,
or
 - 4 Press rotary knob.
- The alarm message remains on screen,
 - The intermittent alarm tone is silenced,
 - The central alarm indicator light goes out,
 - 1 The measured value continues to flash,
 - 2 The yellow alarm LED continues to blink.



When the cause of the alarm has been remedied:

- The warning message disappears.
- The intermittent audible alarm is cancelled.
- The central alarm indicator light goes out.
 - 1 The measured value remains on screen without flashing.
 - 2 The yellow alarm LED goes out.

For other alarms, see "Troubleshooting – Error Messages", page 124.

See also "Alarm Description", page 143.

* If not disabled in the configuration system settings, page 97

Using O2 Control*

WARNING !

Fire hazards from oxygen !

- No open flames or cigarettes ! Textiles, plastics, and oils readily ignite in an oxygen enriched atmosphere and burn with great intensity.
- Keep oxygen valves, connections, and seals free from oil and grease.
- Open valves on O2 cylinders slowly.
- Do not operate Caleo in the presence of flammable anesthetics or disinfectants. Risk of explosion!
- Do not use or store flammable liquids such as alcohol, ether, or acetone inside the Caleo incubator.
- Do not use electrical equipment inside the patient capsule unless this equipment is expressly designed for use in environments that present an explosion hazard.

WARNING !

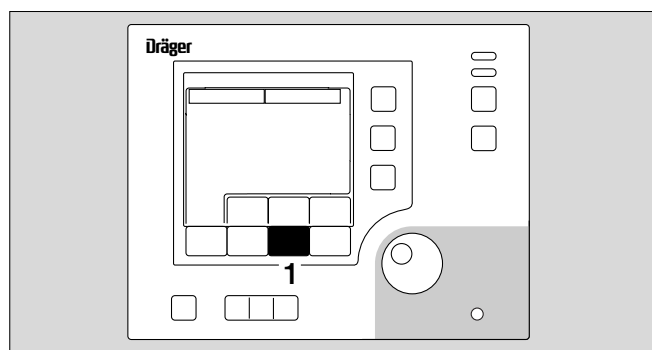
Due to the physiological risks from O2, it is mandatory to monitor O2 concentrations continuously during the administration of O2, either using the integrated O2 measurement and control system or an independent O2 analyzer.

WARNING !

Always take into consideration the physiological risks from the administration of oxygen.
Elevated oxygen concentrations inside the incubator may only be used by or on the order of a physician.
It is absolutely essential that such oxygen therapy be selected and controlled on the basis of the arterially measured oxygen partial pressure in the infant's blood.
This is the only way to minimize the risk of both hyperoxemia (with potential for damage to the eyes by retrolental fibroplasia) and hypoxemia (which might contribute to intraventricular hemorrhage and damage to the infant's brain).

- Connect Caleo DISS oxygen connector via O2 supply hose to an O2 wall outlet (see page 34).
- 1 Press button to set O2 control.

* Available option




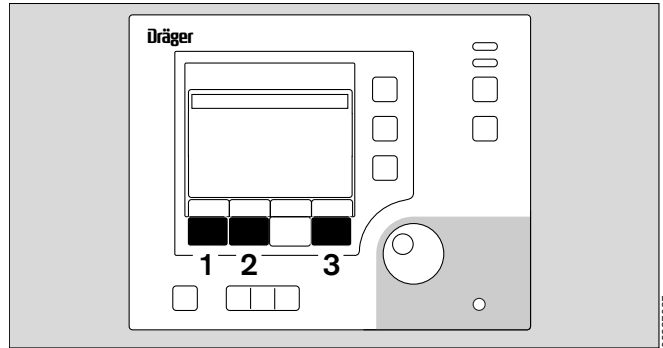
Operation

Using O2 Control

- The measured value and current setpoint for O2 control are represented by bar graphs and numerical values.

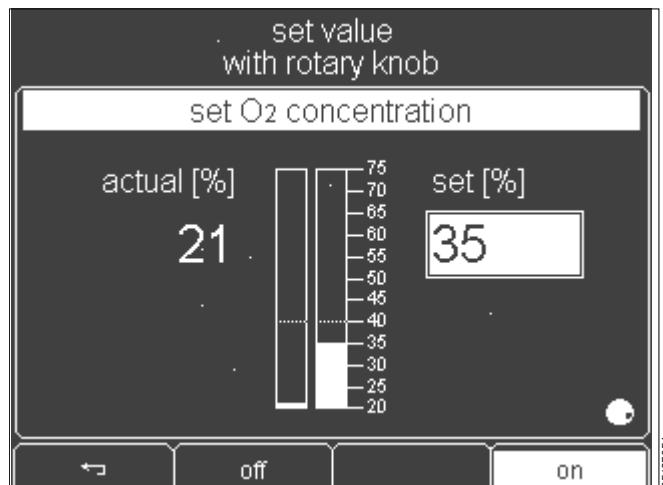
Soft key assignments:

- 1  = New settings are not activated.
- 2 off = Switch off O2 control.
- 3 on = Switch on O2 control.



- After switching on, automatic O2 control is active.
- The following message is displayed at the top of the screen: »set value with rotary knob«.

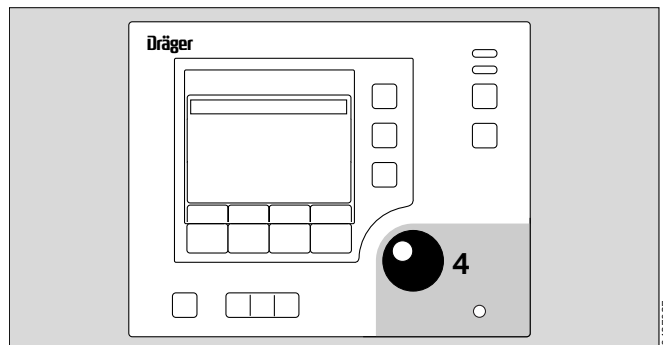
The current measured value is displayed after a few seconds.



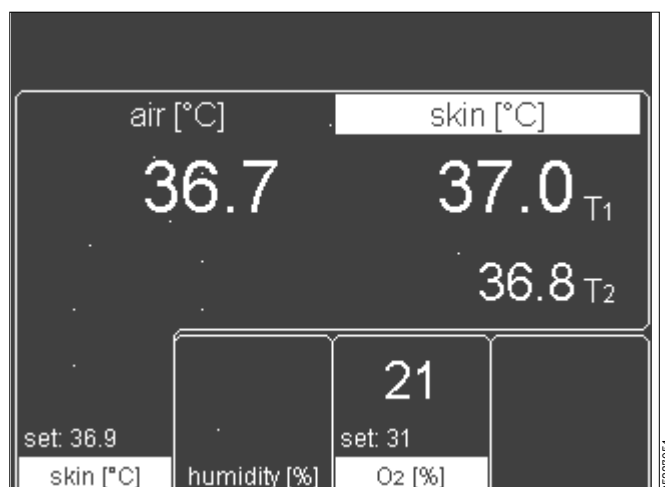
Adjusting the set value

Standard set value range	21 Vol.% to 40 Vol.%
Extended set value range	40.1 Vol.% to 75 Vol.%
Default setting	21 %

- 4 Turn rotary knob clockwise to increase setpoint.
- 4 Turn rotary knob counterclockwise to decrease setpoint.
- 4 Press rotary knob to confirm setpoint.



- Current measured value and setpoint are displayed on screen both as bar graphs and as numerical values.



If value to be set exceeds the standard range:

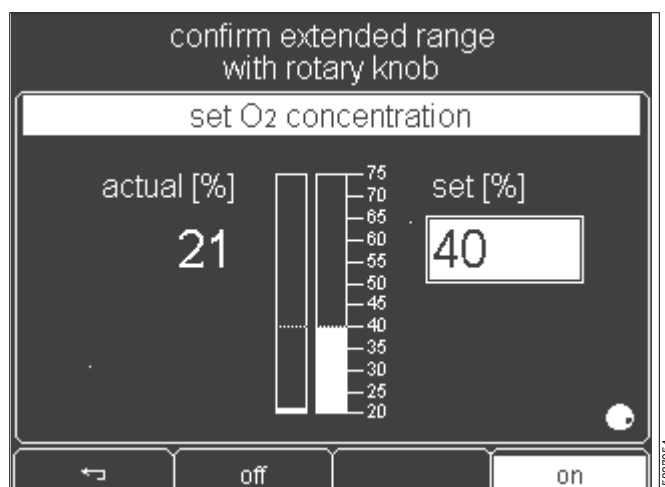
- The following message is displayed at the top of the screen »confirm extended range with rotary knob«.

- Press rotary knob to confirm extended setpoint range.

WARNING !

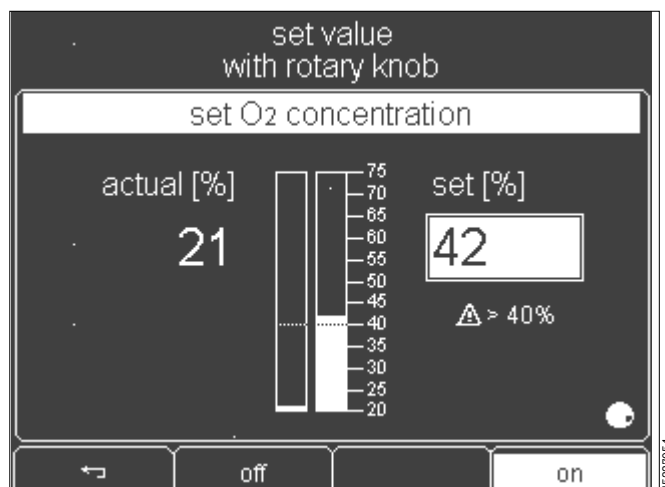
Always keep in mind the physiological risks and fire hazards associated with the use of high O₂ concentrations.

- Turn rotary knob clockwise to continue increasing the setpoint.




- The advisory message » > 40 %« appears on screen.
- The following message appears at the top of the screen »set value with rotary knob«.

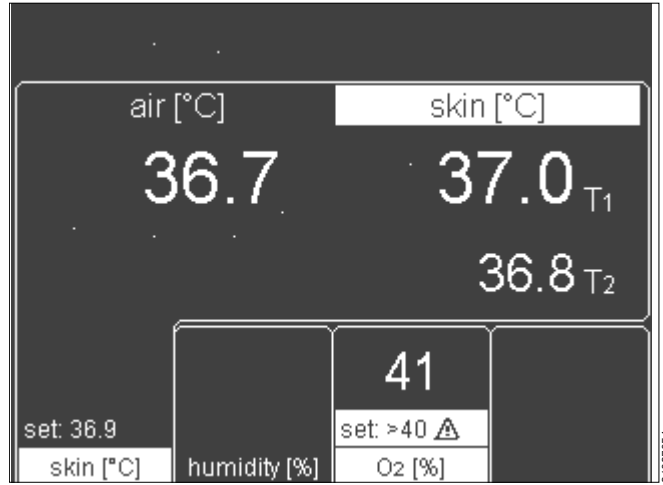
- Press rotary knob to confirm setpoint.



Operation

Using O2 Control

- The display returns to the standard screen. The measured values are displayed.
- The setpoint and »set: >40  « are displayed alternately.



Alarms

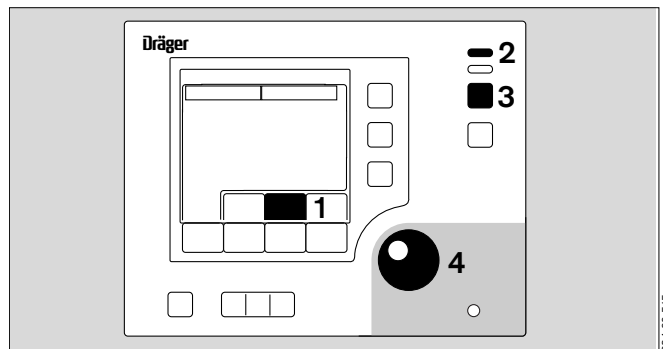
Alarm limits can be changed in the configuration (see page 98).

Example: if the deviation between the set and measured O₂ concentration exceeds ± 5 %*:

- The screen displays the warning message »Oxygen deviation above 5 %«,
- An alarm tone sequence (5 beeps) starts,
- The central alarm indicator lights up**,
 - 1 The measured value starts flashing,
 - 2 The red alarm LED starts blinking.

The intermittent audible alarm can be silenced for 2 minutes:

- 3 Press key to silence intermittent audible alarm,
- or
- 4 Press rotary knob.
- The warning message remains on screen,
 - The intermittent alarm tone is silenced,
 - The central alarm indicator goes out,
 - 1 The measured value continues to flash,
 - 2 The red alarm LED continues to blink.



When the measured value has returned to a value within the alarm threshold of ± 5 Vol. %:

- The warning message disappears.
- The intermittent alarm tone is cancelled.
- The central alarm indicator goes out.
 - 1 The measured value remains on screen without flashing.
 - 2 The red alarm LED goes out.

For other alarms, see "Troubleshooting – Error Messages", page 124.

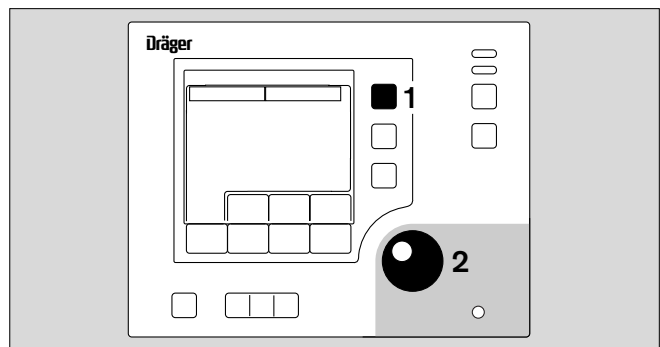
See "Alarm Description", page 143.

* The numerical values in this description are examples.
See "Configuring alarm settings", page 98.

** If not disabled in the configuration system settings, page 97

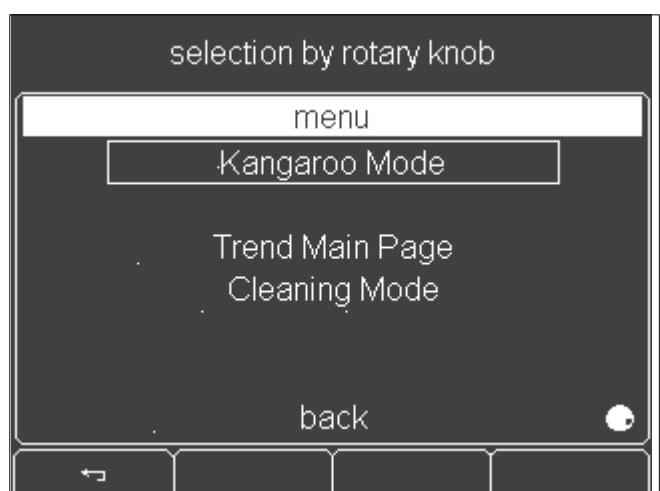
Selecting Menus

- 1 Press »menu« key to select menus.



The required mode can be selected from the menu displayed.

- 2 Turn rotary knob to select item.
- 2 Press rotary knob to confirm selection (to activate item).



Kangaroo Mode™

WARNING !

When using Kangaroo Mode, central temperature of the infant, who is outside the controlled climate of the incubator, must be monitored constantly. Particular attention must be paid to critical care patients' vital parameters, especially a critical O₂ partial pressure. Ensure that all cables and hoses are routed correctly and safely.

NOTE: In Kangaroo Mode the incubator is always operating in air temperature control mode.

If Caleo was previously operating in air temperature mode, the air temperature setpoint will remain active while in Kangaroo Mode.

If Caleo was previously operating in skin temperature mode, the average of the last 3 minutes of air temperature values will be used as setpoint. The yellow skin (tummy) temperature sensor and the peripheral (toe) temperature sensor can be used in Kangaroo Mode to monitor the skin temperature of the infant. Several specific alarm limits are available for Kangaroo Mode and can be set individually in configuration mode. (see page 98).

Operation

Selecting Menus

The previously set values for

- Humidity (page 74) and
- O₂ (page 78) are retained in Kangaroo Mode.

The previous set value for skin temperature control is stored in buffer memory.

Activating Kangaroo Mode

For a description of Kangaroo Mode, see page 138.

- 1 Press »menu« key to display the main menu.

Select "Kangaroo Mode" from the menu.

- 2 Turn rotary knob to select item.
- 2 Press rotary knob to confirm and activate item.

- The screen displays the following advisory message:
»You are leaving the current mode. Please confirm the new Kangaroo Mode with rotary knob«.

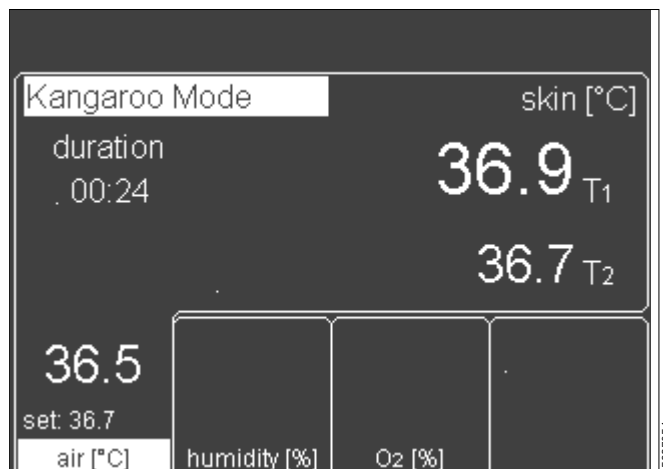
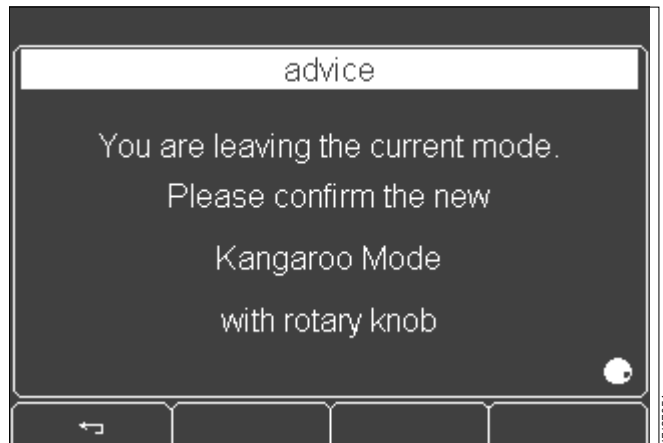
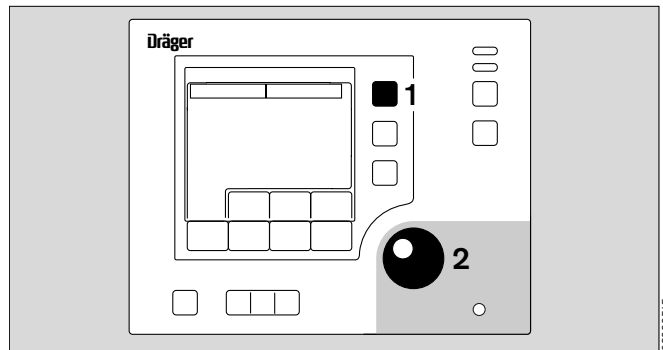
- 2 Press rotary knob to confirm Kangaroo Mode.

- Kangaroo Mode is highlighted on screen by a light background when activated.
- The duration of Kangaroo Mode can be displayed on the screen in minutes and seconds (mm:ss).

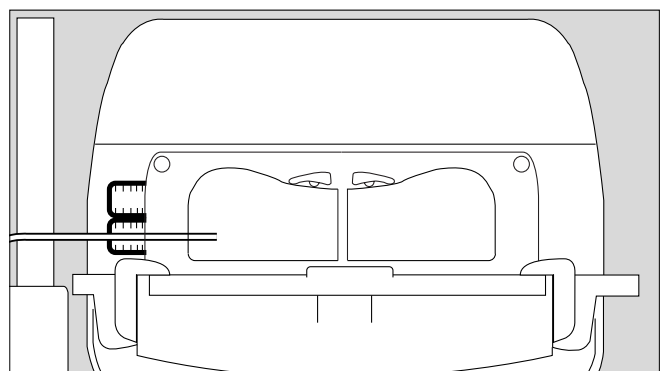
Suppressing of alarms is automatically activated, i.e. all alarms occurring within the next 5 minutes for the following parameters

- Air temperature deviation
- Kangaroo Mode
- O₂ deviation

are automatically displayed as "acknowledged" for the respective period. see "Suppressing Alarms", page 102.



- Tubing grommets can be removed from the corner segments of the hood so that hoses and cables connected to the infant remain well organized during Kangaroo Mode.



Alarms

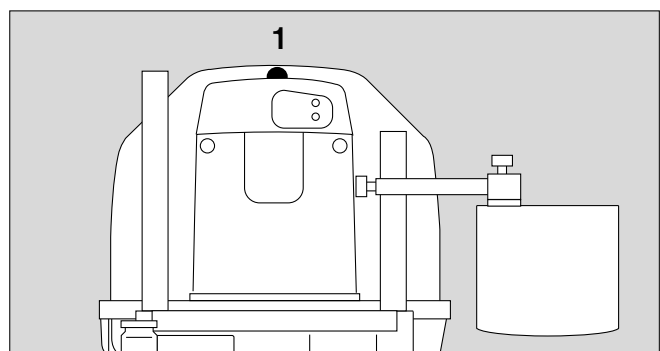
Alarm limits can be changed in the configuration (see page 98).

If the skin temperature of the yellow skin temperature sensor (skin 1) falls below the alarm limit set in the configuration:

- The screen displays the warning message:
»Skin 1 temperature below 36.0 °C «*
- An alarm tone sequence (3 beeps) starts.
- 1 The central alarm indicator lights up**.
- 2 The measured value starts flashing.
- 3 The yellow alarm LED starts blinking.

The intermittent audible alarm can be silenced for 15 minutes.

- 4 Press key to silence intermittent alarm tone
- or
- 5 Press rotary knob.
- The warning message remains on screen.
- The intermittent alarm tone is silenced.
- 1 The central alarm indicator goes out.
- 2 The measured value continues to flash.
- 3 The yellow alarm LED continues to blink.

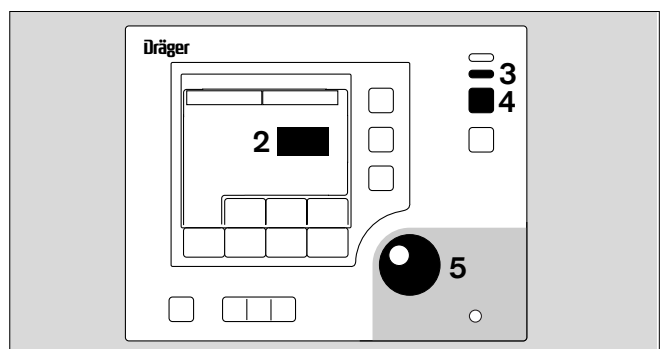


When the measured value returns above the alarm limit:

- The warning message disappears.
- The intermittent alarm tone is cancelled.
- 1 The central alarm indicator goes out.
- 2 The measured value remains on screen without flashing.
- 3 The yellow alarm LED goes out.

For other alarms, see "Troubleshooting – Error Messages", page 124.

See also "Alarm Description", page 143



* The *numerical values* in this description are examples.
See "Configuring alarm settings", page 98.

** If not disabled in the configuration system settings, page 97

Operation

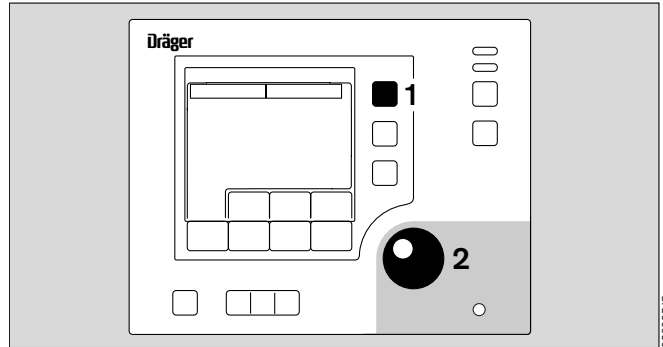
Selecting Menus

Ending Kangaroo Mode

- 1 Press »menu« key to display menu list.

Select item »Back to air mode« or »Back to skin mode« from the displayed list.

- 2 Turn rotary knob to select item.
- 2 Press rotary knob to activate item.



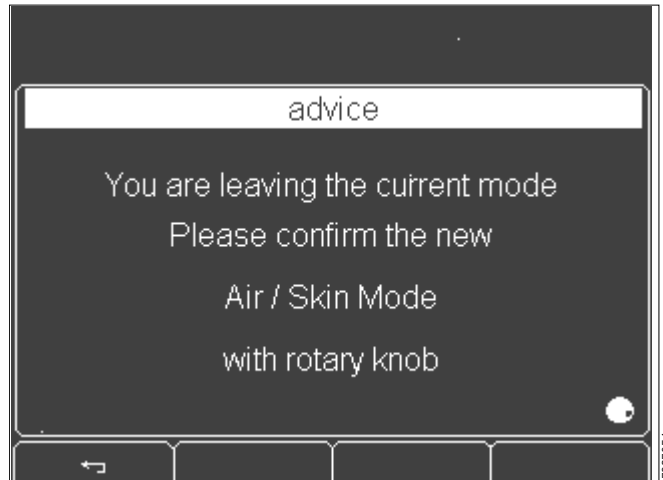
03929515

- The screen displays the advisory message:
»You are leaving the current mode.
Please confirm the new Air/Skin Mode with rotary knob«.

- 2 Press rotary knob to exit Kangaroo Mode.

The former operating status with the previously set values is reactivated. The display returns to the standard screen.

After quitting Kangaroo Mode, reinsert the tubing grommets in the corner segments of the hood.



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- To maintain Kangaroo Mode = press »←« key.


Or

- Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press rotary knob. If the rotary knob is not pressed, the display will automatically return to the standard screen after 7 seconds, and the previous setpoint will be retained.

Trend display

The display of trends serves to graphically and numerically illustrate measured parameters. The data window shows the most recent data in the selected time interval. In addition, the current measured values and setpoints are displayed.

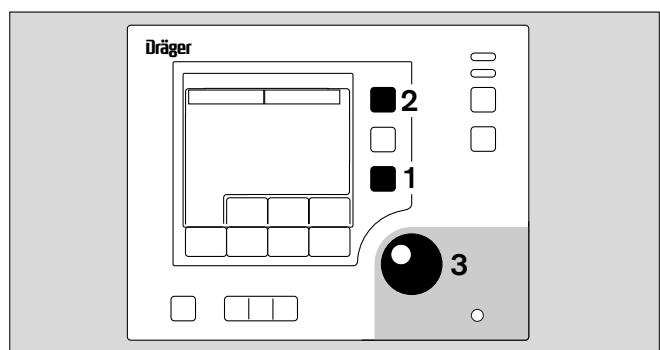
Switching between standard and trend screen

- 1 Press »  « key to display trend.

Selecting trend display

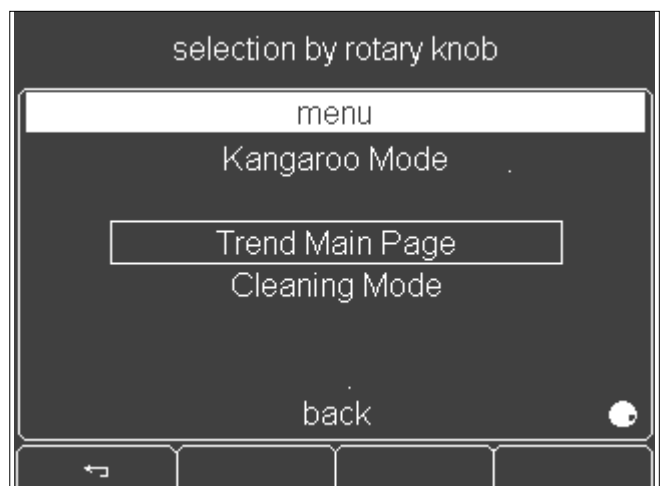
To select the trend you wish to display:

- 2 Press the »menu« key to open the menu selection.



Select item "Trend Main Page" from the displayed menu.

- 3 Turn rotary knob to select menu item.
- 3 Press rotary knob to activate menu item.




- Select the desired trend display from the displayed list.

Defaults:

- Air temperature trend
- Zoom factor: 3 hours

- 3 Turn rotary knob to select trend.
- 3 Press rotary knob to activate trend.

- Press »  « key to return to menu selection.




Operation

Selecting Menus

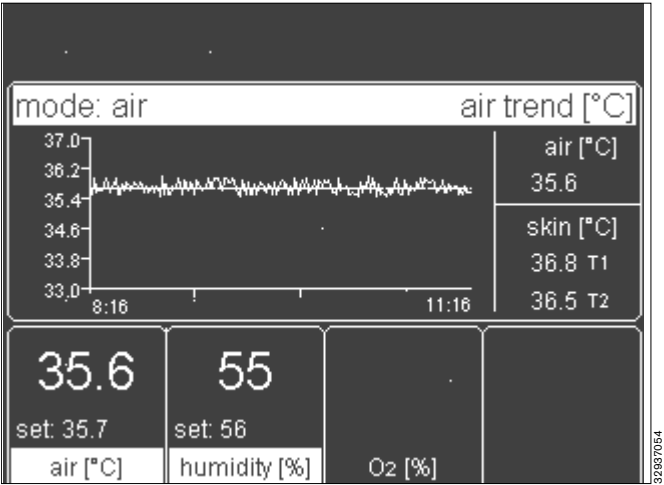
- The air temperature trend of the last 3 hours is displayed.

The data window on the right shows the current measured values of air and skin temperature.

- T1: Yellow skin temperature sensor (Skin 1)
- T2: White peripheral sensor (Skin 2)

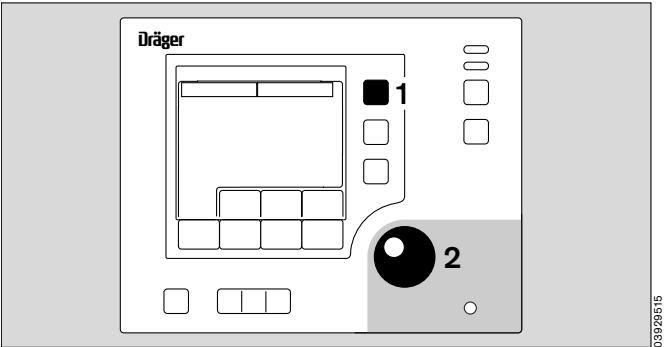
- Press »  « button to exit trend display mode.

The display returns to the standard screen.



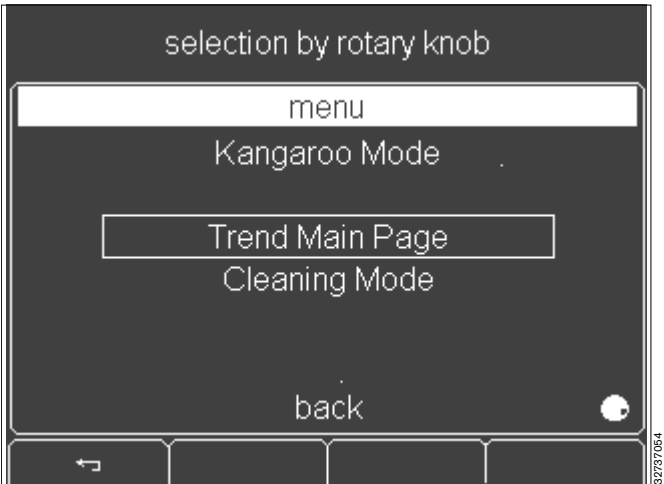
Setting the displayed time interval (zoom)

- 1 Press »menu« button to display menu selection.



Select item "Trend Main Page" from the displayed menu.

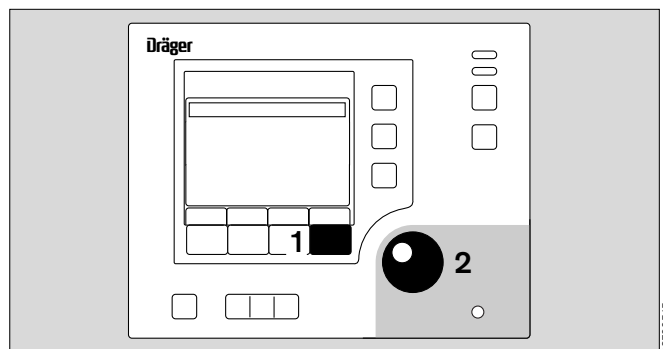
- 2 Turn rotary knob to select menu item.
- 2 Press rotary knob to activate menu item.



- Select desired trend from the displayed list.

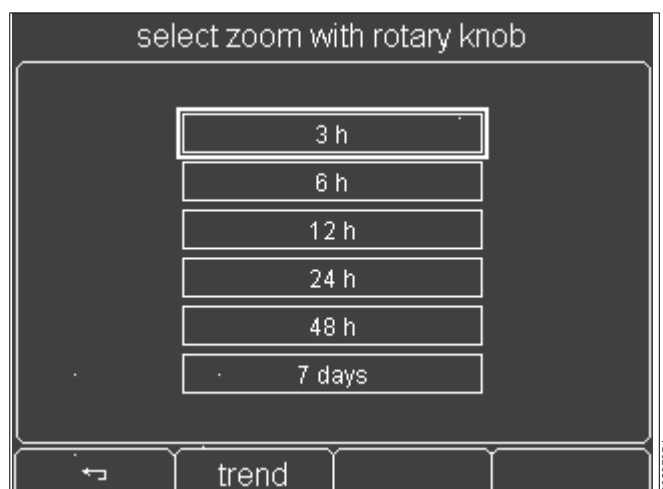


- Press »←« key to return to menu selection.
- Or,
- 1 press key to display zoom menu.



- Select desired zoom factor from the menu.

- 2 Turn rotary knob to select zoom factor.
- 2 Press rotary knob to activate zoom factor.

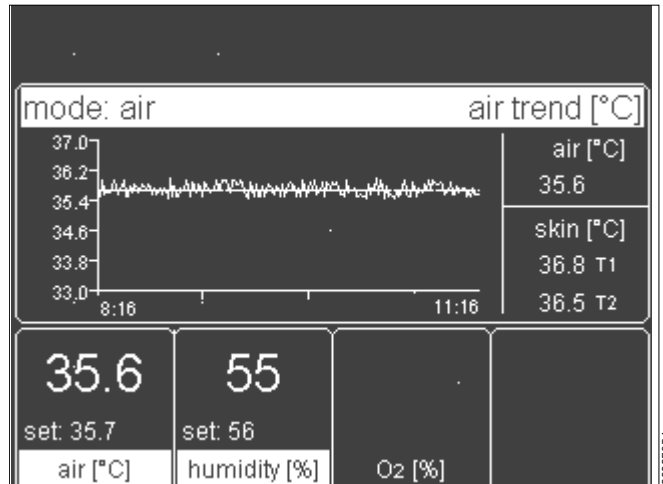


- Press »←« soft key to return to menu selection.
- Press »trend« soft key to return to Trend Main Page.

Operation

Selecting Menus

- In the illustrated example, the trend for the air temperature over the last 3 hours will be displayed.
- T1: Yellow skin temperature sensor (skin 1)
- T2: White peripheral sensor (skin 2)



Trend analysis



Trend analysis is used for graphically and numerically displaying measurement parameters and associated setpoints. The data time window can be moved freely across the last 7 days.

Trend analysis can therefore be used to evaluate thermo-monitoring data.

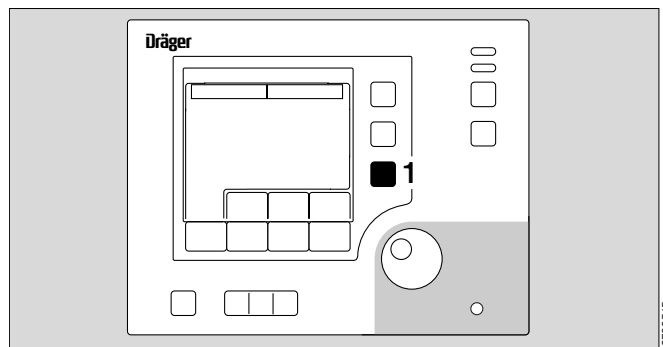
The following parameters can be selected:

- Skin temperature 1
(yellow skin temperature sensor, skin 1, T1)
- Peripheral temperature or skin temperature 2 (for twins)
(white temperature sensor, skin 2, T2)
- Air temperature
- Relative humidity (rel. %)*
- O2 concentration (vol %)*.

NOTE: While trend analysis is in progress, no current measured values (air, skin, etc.) are displayed. The numerical values displayed are values from past readings.

If no key is pressed for 2 minutes, the display automatically reverts to the standard screen.

- 1 Hold key down for 4 seconds to activate trend analysis.



* Available option

- The trend graph for the selected measured value is displayed on screen.

Default measured value:

trend 1	Skin temperature
trend 2	Air temperature
zoom	3 hours

The selected value is displayed as a trend graph. In this graph, the trend curve of the measured value is overlaid on the corresponding setpoint curve.

Time cursor:

The time cursor is displayed as a vertical dotted line marking a precise point of time on the graph's time axis.

- Turn rotary knob to move the time curve on the time scale.

The point in time marked by the cursor line is specified underneath the dotted line with date and time. Start and end time for the current time window are specified underneath the trend graph to the right and left, respectively.

If the time cursor is moved beyond the displayed time range, the screen adapts automatically and displays the new time range:

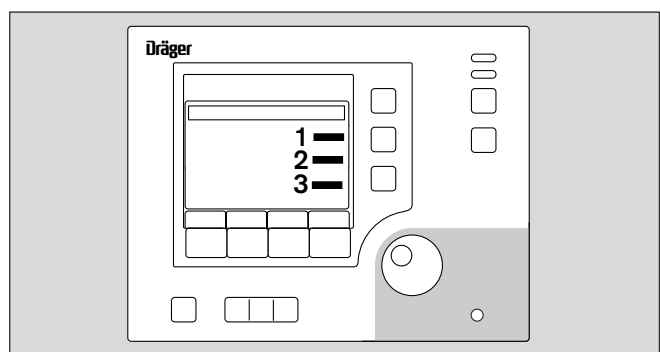
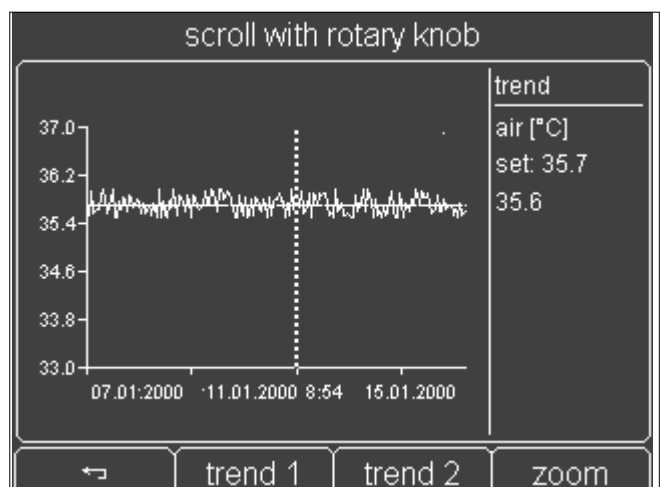
- Turn rotary knob counterclockwise to display a less recent time range.
- Turn rotary knob clockwise for a more recent time range.

Data window:

The time cursor is associated with a data window situated to the right of the displayed trend. This data window shows the numerical values pertaining to the time marked by the time cursor.

The following values are displayed in the data window:

- 1 Name of the selected parameter
- 2 Set value of this parameter at the marked time
- 3 Measured value of the parameter at the marked time




Operation

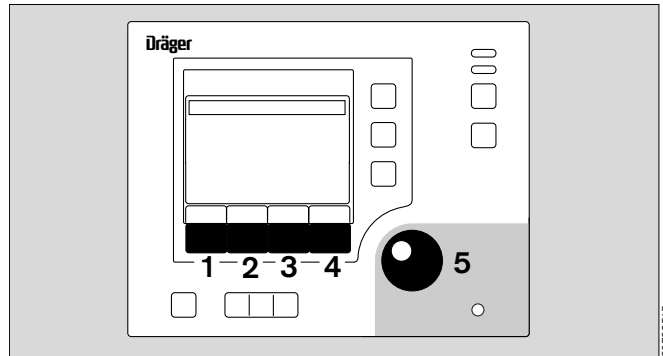
Selecting Menus

Trend selection

A trend graph can be selected with soft keys.

Soft key assignments:

- 1  = Cancel. New settings will not be activated.
- 2 trend 1 = Select trend 1
- 3 trend 2 = Select trend 2
- 4 zoom = Select time interval



To select trend 1:

- 2 Press soft key to display trend 1 menu.
The following parameters can be selected as "trend 1":
 - air
 - skin
 - humidity*
 - oxygen*
 - weight*

- 5 Turn rotary knob to select trend 1.
- 5 Press rotary knob to confirm (activate) selection.

The newly selected trend will be displayed on screen.



Select trend 2:

- 3 Press soft key to display trend 2 menu.
The following parameters can be selected as "trend 2":
 - air
 - humidity*
 - oxygen*
 - weight*
 - disable

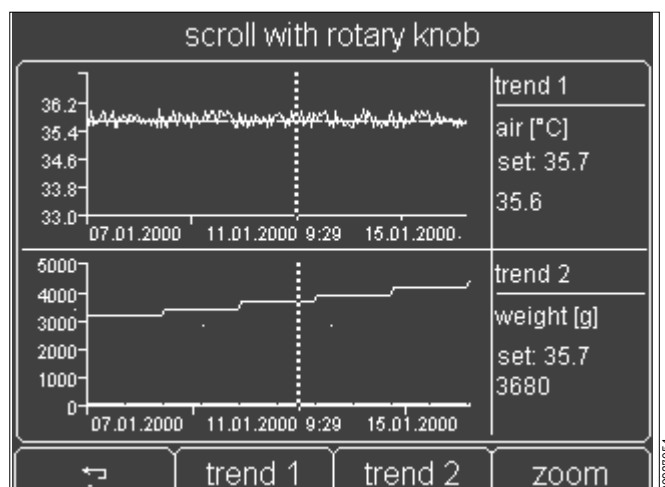
- 5 Turn rotary knob to select trend 2.
- 5 Press rotary knob to confirm (activate) selection.



* Available option

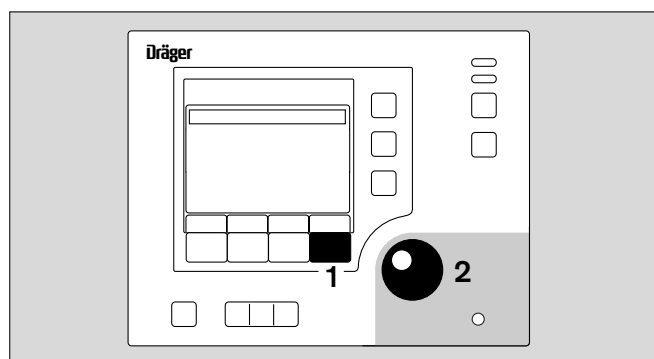
The newly selected trend is displayed on the screen below trend 1. In addition, a second data window containing the respective numerical parameters is opened next to trend 2. Time cursor and time range (zoom) are the same for both trend displays.

The »disable« option removes trend 2 from the screen, so that only trend 1 is displayed.



Selecting the time interval (zoom)

- 1 Press soft key to open the zoom menu.



The following intervals of time can be selected for the time window (zoom) function:

3; 6; 12; 24; 48 hours, or 7 days

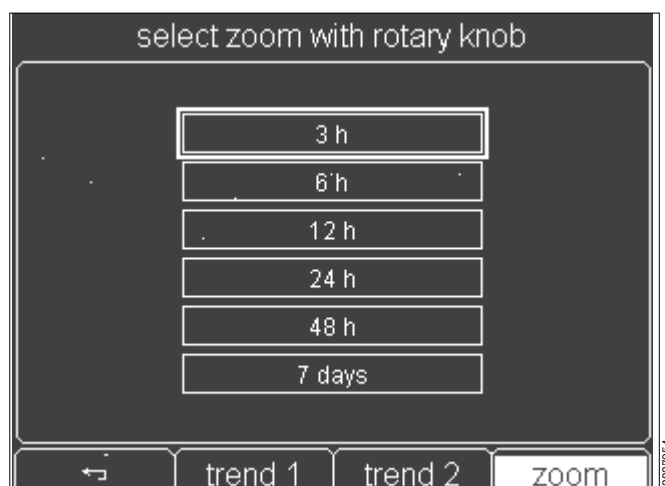
- 2 Turn rotary knob to select zoom interval.

- 2 Press rotary knob to activate zoom.

The selected trends will then be displayed in the newly selected time window.

All data going back a maximum of 7 days can be displayed. The individual measuring points together with the associated data for the data window are displayed.

When displaying the measured weight values, up to 30 values can be stored and displayed as a trend. Values between the individual measured values are interpolated.



Operation

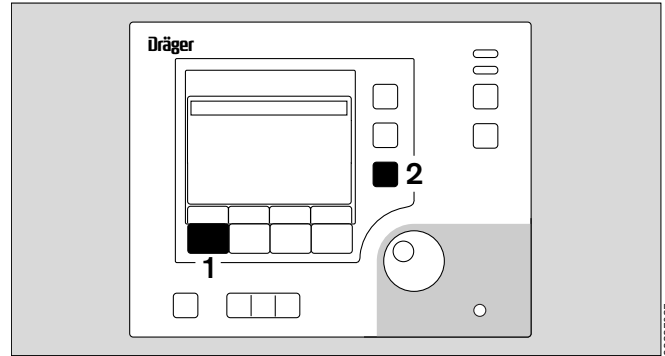
Selecting Menus

Ending trend analysis

To exit trend analysis

- 1 Press »←« soft key to return to menu,
or
- 2 press key to terminate trend analysis.

Alternatively, if no key is pressed for 2 minutes, the display will automatically revert to the standard screen.



Cleaning mode*

Cleaning mode is only available if Caleo is equipped with humidity control.

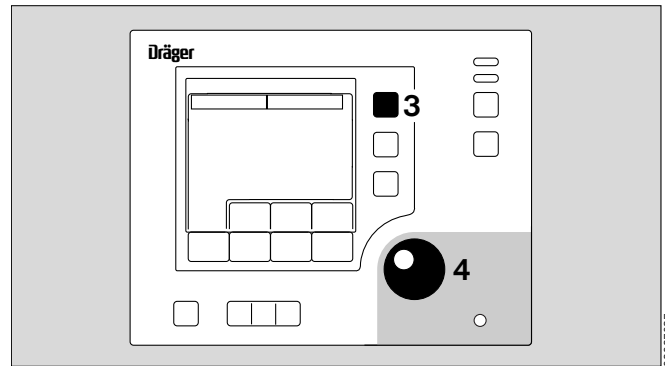
WARNING!

Cleaning mode may only be used while Caleo is not occupied by a patient.

In cleaning mode the water heater is boiled empty and then cooled.

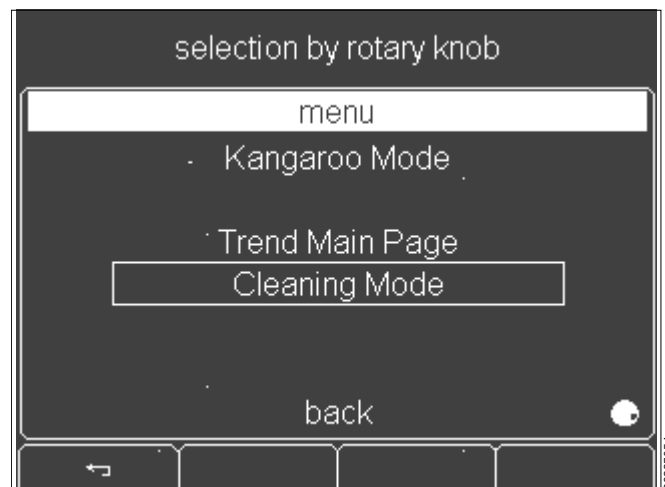
Cleaning mode lasts about 60 minutes.

- 3 Press »menu« key to display the main menu.



Select "Cleaning Mode" from the displayed menu.

- 4 Turn rotary knob to select item.
- 4 Press rotary knob to confirm (activate) item.

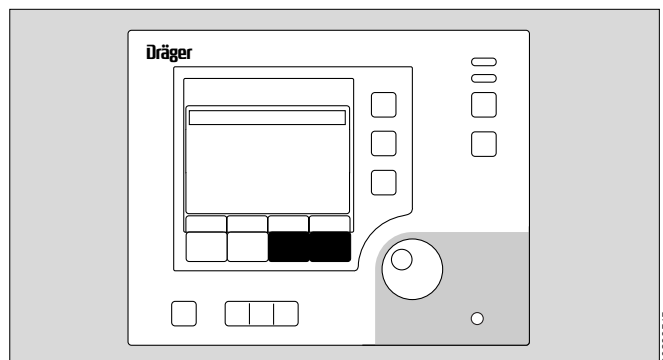


* Available option

- The required operating steps are specified on screen:
- Disconnect luer lock connector from the apparatus.



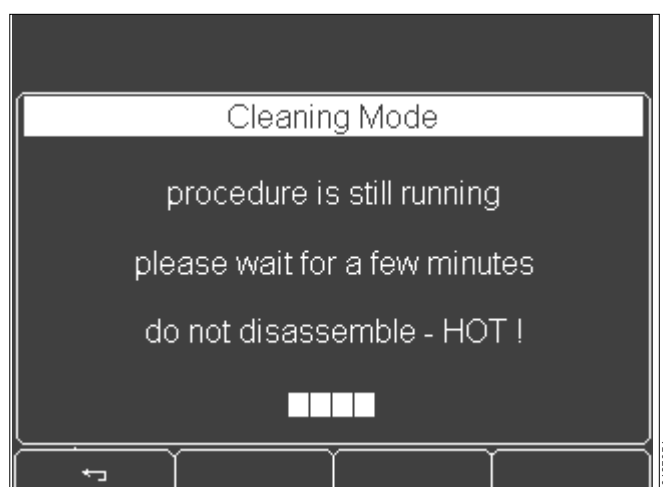
- Press both soft keys simultaneously to start cleaning mode.



The water heater is boiled dry.
The heater is then cooled.

WARNING!

Risk of burns upon contact with the heater!
Do not disassemble Caleo while in cleaning mode.

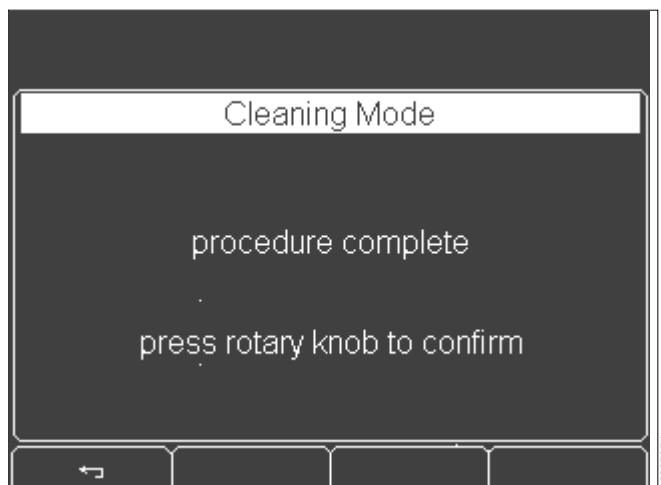


Operation

Selecting Menus

- A screen message will indicate when the cleaning procedure has been completed.
- Press rotary knob to confirm end of cleaning mode.

Caleo performs a restart.



After ending Cleaning Mode:

- Disinfect and clean Caleo (see "Disinfecting / Cleaning / Sterilizing", page 108).

Configuration

In configuration mode, you may set:

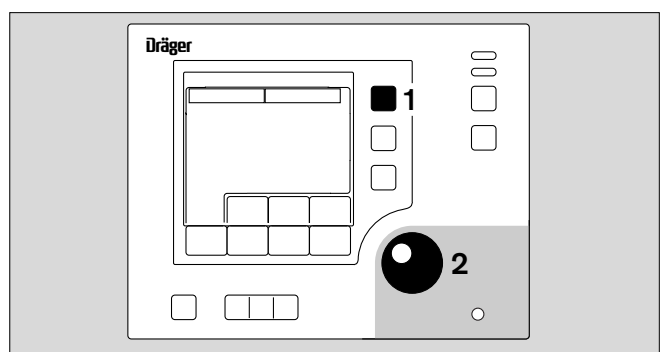
- language, date, and time,
- system parameters, and
- alarm parameters.

Additionally, information may be obtained on:

- O₂ sensors, and
- the software version.

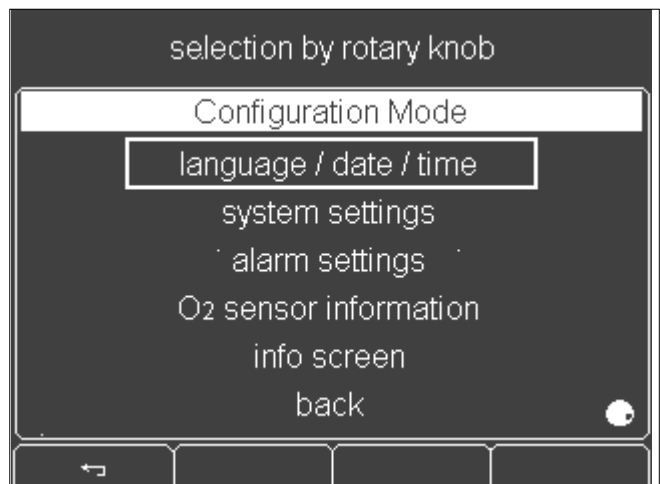
Activating configuration mode

- 1 Hold down »menu« key for 4 seconds to display configuration mode.



The individual configuration parameters may now be selected.

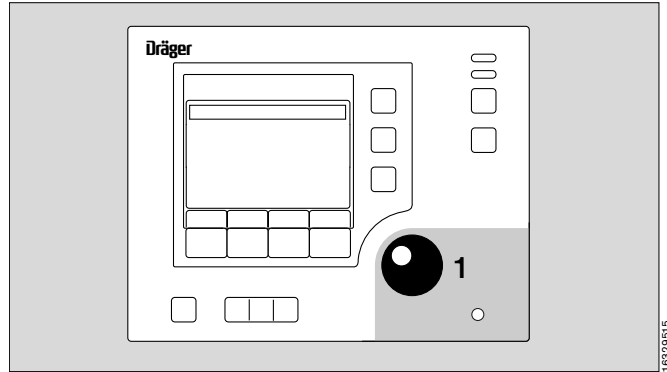
- 2 Turn rotary knob to select configuration parameter.
- 2 Press rotary knob to activate configuration parameter.



- Press »←« key to cancel selection.
- The display returns to the standard screen.

Configuring language/date/ time

- 1 Turn and press rotary knob to select language/date/time.



- The language selection is highlighted by a bold frame.

- 1 Turn rotary knob to select language.
- 1 Press rotary knob to confirm language.

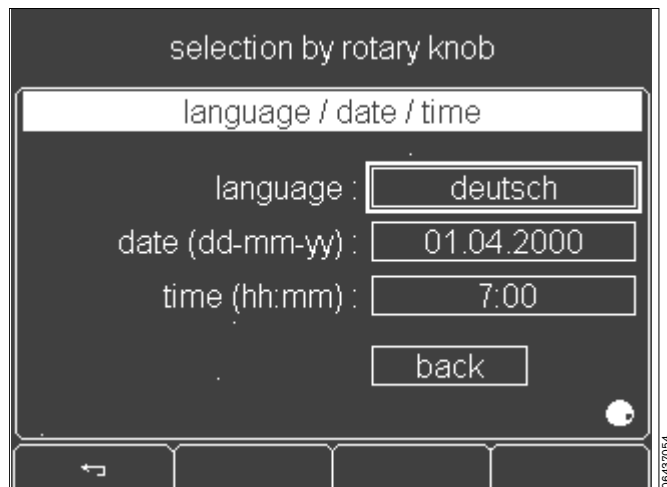
- The selected language is displayed on screen.

Date and time are set using the same procedure.

- 1 To save settings, turn rotary knob to »back«, then press the rotary knob to confirm.

- To cancel selection, press »←« soft key.

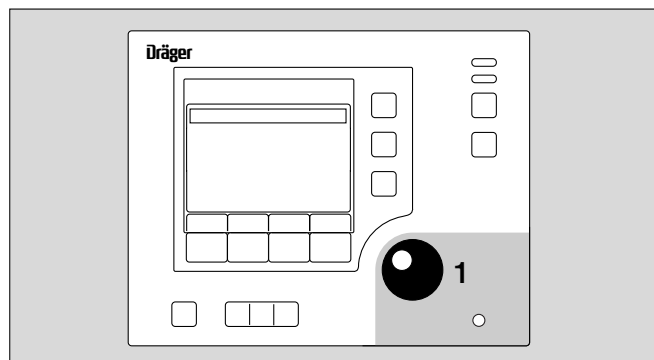
- The display returns to the configuration mode selection menu (see page 95).



Configuring system settings

From the configuration mode selection menu:

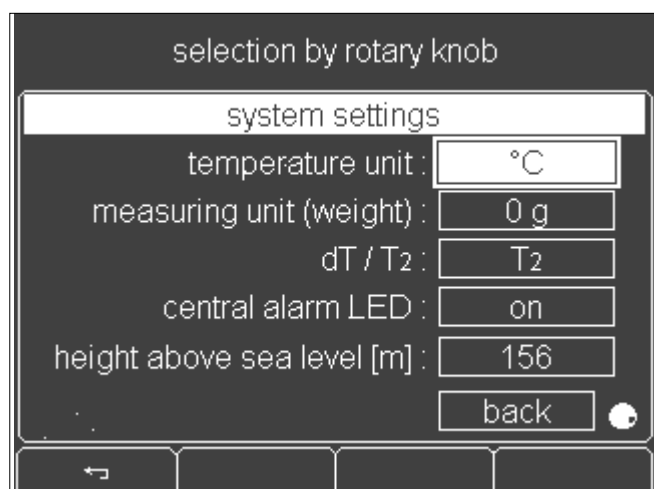
- 1 Turn and press rotary knob to configure unit of temperature.



- The temperature unit is highlighted by a light background.

- 1 Turn rotary knob to select unit.
- 1 Press rotary knob to confirm unit.

- The selected unit is displayed on screen.



Unit of weight, display of dT/T₂, central alarm indicator, and elevation above sea level are configured in the same fashion.

- The unit of weight can only be configured if Caleo is equipped with the integrated infant scale*.
- When using two skin temperature sensors, T₂ or the difference between T₁ and T₂ (dT) can be displayed in addition to the value of T₁.
- If the central alarm LED is disabled, alarm situations are only indicated by the blinking display for the measured value, blinking alarm LED on the control unit, and the audible alarm.
- Elevation above sea level can only be set if Caleo is equipped with integrated O₂-control. An incorrectly set elevation will reduce the measuring accuracy of the O₂ sensors (approximately 1.5 % additional error at 3280 ft / 1000 m).

- To cancel a selection, press »←« soft key.

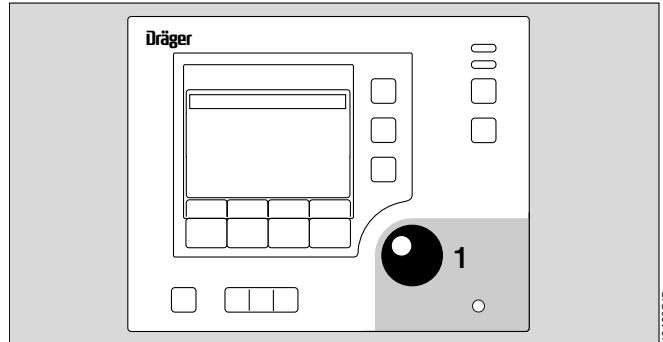
- The display returns to the configuration mode selection menu (see page 95).

* available option

Configuring alarm settings

From the configuration mode selection menu:


- 1 Turn and press rotary knob to configure alarms.



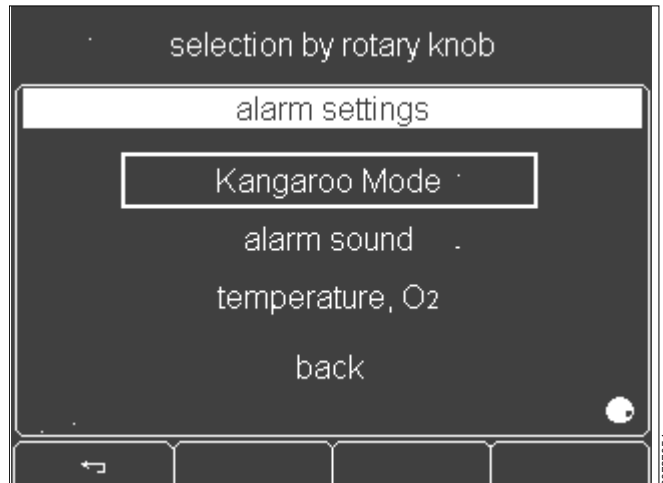
- The menu that is then displayed allows the user to select Kangaroo Mode alarm settings, the initial volume of audible alarms and the alarm thresholds for temperature control and O₂ control.

- 1 Turn rotary knob to select menu item.

- 1 Press rotary knob to confirm menu item.

- To cancel a selection, press »  « soft key.

- The display returns to the configuration mode selection menu (see page 95).



Kangaroo Mode:

Setpoint ranges:

Skin alarm T1 min 33 °C to 37 °C and off

Skin alarm T2 min 33 °C to 37 °C and off

dT alarm min -2 °C to 2 °C and off

dT alarm max 2 °C to 5 °C and off

Default values: last settings

The *text* items in the description that follows are examples:

- 1 Select skin alarm *T1 min* (lower alarm limit for skin temperature) = turn and press the rotary knob.


- When selected, the setting for "alarm skin *T1 min*" is highlighted by a bold frame.

- 1 Turn rotary knob to select alarm setting.

- 1 Press rotary knob to confirm alarm setting.

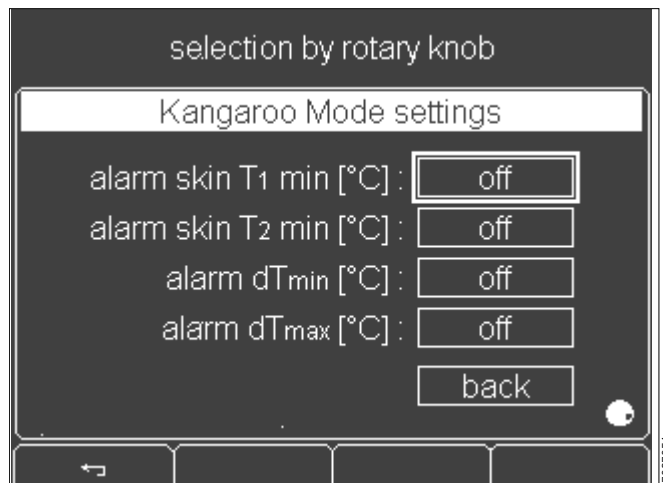
The display returns to the alarm settings menu (see above).

The other alarms are set using the same method.

- To cancel a selection, press »  « soft key.

- The screen returns to the configuration mode selection menu (see page 95).

For a description of Kangaroo Mode alarms, please refer to page 139.



Audible alarm volume:

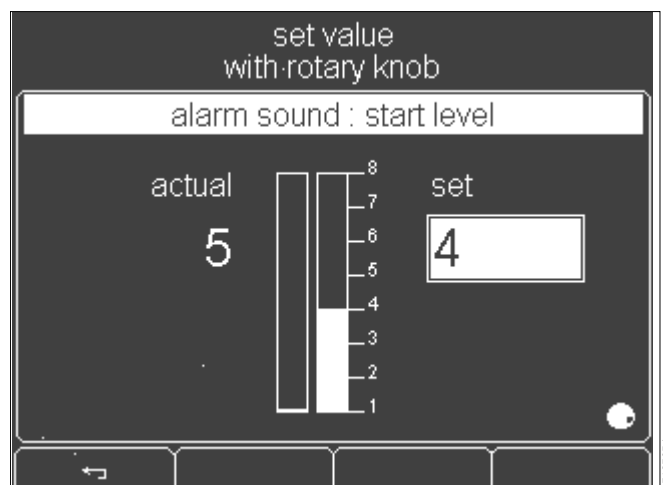
Setpoint range: 1 to 8

Default: 1

- The initial alarm volume is highlighted by a light background.
- Turn rotary knob to set audible alarm volume default to be in effect at start-up.
- Press rotary knob to confirm initial volume setting.

The screen returns to the alarm settings menu (page 98).

- To cancel selection, press »←« soft key.
- The display returns to the configuration mode selection menu (see page 95).

**Alarm limits:**

Setpoint ranges:

Air temperature deviation –1.5 or –2.5 °C

Skin temperature deviation ±0.3 to 1.0 °C

O2 deviation* ±3 % or ±5 %

Default values:

Air temperature deviation –1.5 °C

Skin temperature deviation ±0.5 °C

O2 deviation* ±5 %

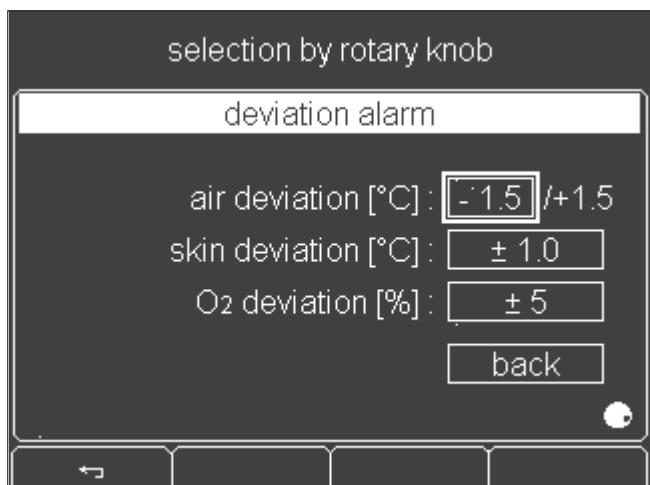
- Turn and press rotary knob to select alarm limit for air/skin temperature and O2.
- The setting for the air temperature alarm threshold is highlighted by a bold frame.

- Turn rotary knob to select new threshold.
- Press rotary knob to confirm air temperature deviation threshold.

The screen returns to the alarm settings menu (page 98).

The other alarm limits are set in the same fashion.

- To cancel selection, press »←« soft key.
- The display returns to the configuration parameter menu (see page 95).



* Available option

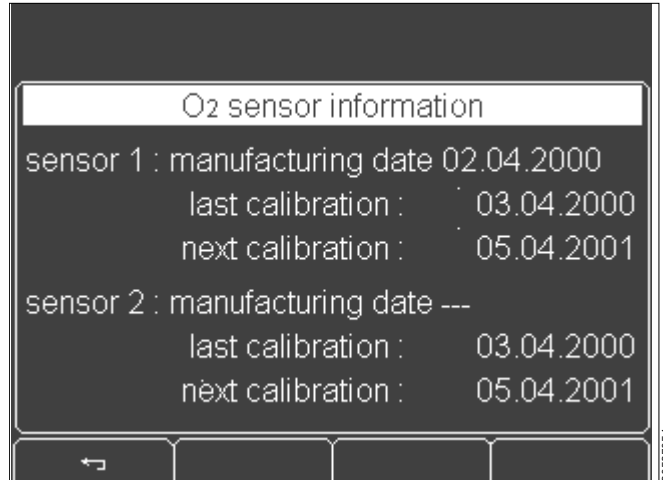
Viewing O2 sensor information*

From the configuration mode selection menu:

- Turn and press rotary knob to select "O2 sensor information".

The screen displays the following information for the O2 sensors used:

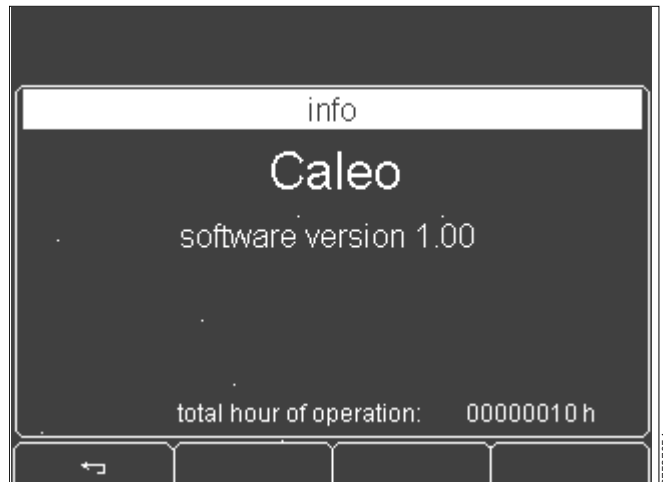
- Date of manufacture
- Date of last calibration
- Date of next calibration.



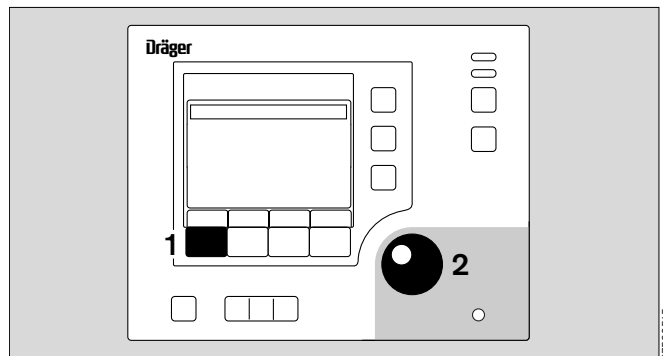
Viewing software information

From the configuration mode selection menu:

- Turn and press rotary knob to select "info screen"
- The software version and the number of operating hours are displayed on screen. Where applicable, this screen contains additional information on service intervals. Further information on this subject is provided in the service documentation.



- 1 Press soft key to return to configuration mode selection menu,
- or
- 2 press rotary knob.
- The display returns to the configuration mode selection menu (see page 95).



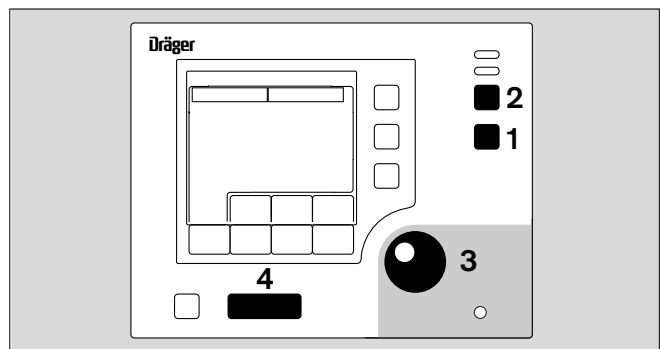
* Available option

Keypad Lock



Locking keypad

- 1 Press key to prevent any on-screen setting.
- 1 The LED in the key lights up.
 - After 4 seconds, all screen functions are locked, **except for:**
 - 1 Keypad lock
 - 2 Alarm silencing
 - 3 Rotary knob
 - 4 Bed tilt.
- 1 The LED in the key remains lit.



Enabling keypad

- 1 Press key to enable on-screen settings.
- 1 The LED in the key goes out.
 - After 4 seconds, the screen functions can be changed. The LED in the key remains off.

Suppressing Alarms



- 1 When pressing this key while an alarm is active:
 - The audible alarm is silenced.
 - The central alarm indicator goes out.*
- 1 The LED in the button is not lit.

The maximum duration for suppressing an alarm depends on the type of the alarm. Suppression of an alarm ends with the alarm, and does not continue on as preemptive silencing of alarms.

- 1 Pressing this key if no alarm is active (preemptive alarm silencing):

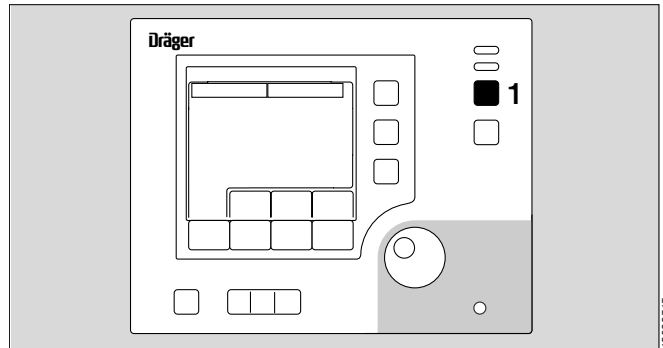
For the following types of alarms:

- Air temperature deviation,
- Skin temperature deviation,
- O₂ deviation,

no audible alarm will sound and the central alarm indicator light will not light up for all alarms occurring in the next 4 minutes.

However: The respective alarm messages will be displayed on screen, the measured value will start flashing, and the alarm LED will start blinking.

- 1 The LED in the button will be lit.



WARNING !

While alarm suppression is active, the operator of the incubator must still assume responsibility for proper patient care and safety in the event of an alarm. Failure to identify and correct alarm situations may result in patient injury.

* If not disabled in the configuration system settings, page 97

Integrated Infant Scale*



The weighing scale is located directly underneath the bed. In the weighing process, the entire bed and the items placed on top of it are weighed with the infant. However, the weight of these articles are deducted again as soon as the infant is lifted off the bed (tare weight), so that precise weighing of the infant is possible.

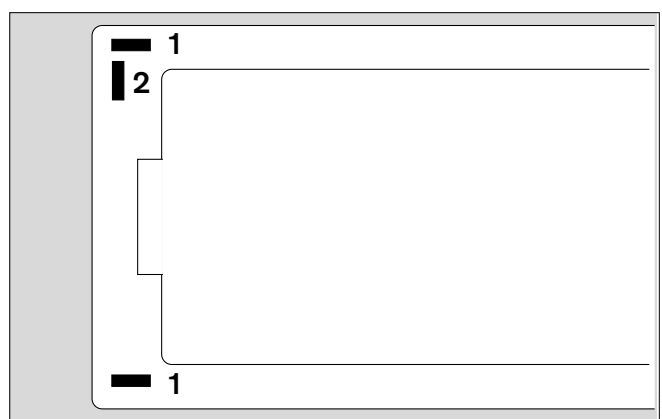
Before weighing, check that the bed is fully pushed in and that it is in the horizontal position.

The scale must be verified regularly with a test weight.

The spirit levels show whether the bed is positioned horizontally.

- 1 Levels for the horizontal alignment of Caleo in the transverse axis.
- 2 Level for the horizontal alignment of Caleo in the longitudinal axis.

To level the bed, see page 43.



During the weighing process, Caleo must not be exposed to any vibrations.

During the weighing process, no objects may be placed on the bed surface.

During the weighing process, no objects may be placed between the bed and the housing.

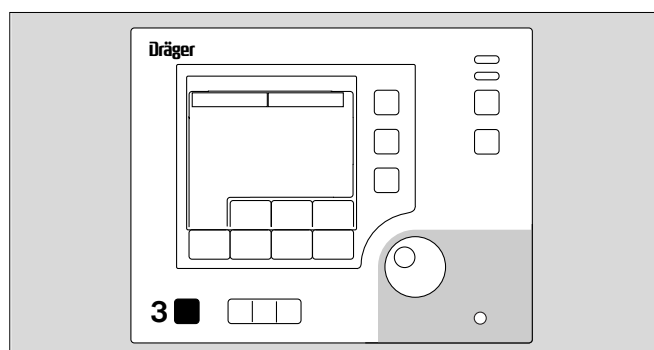
Weighing accuracy may be adversely affected when using the ventilator circuit support arm.

Starting the weighing procedure

- Remove supply lines, supply line brackets or other articles from the bed,
- 3 Press key to activate the weighing process.

If the scale is **not** ready for operation, this function cannot be activated.

- A single audible alarm (1 beep) will sound
- On screen, an advisory message is displayed:
»Scale inop«.




* Available option

Operation

Integrated Infant Scale

- Press rotary knob to acknowledge advisory message.

During the weighing procedure, the user is guided through the sequence of operating steps by the following prompts:

- Please adjust Caleo to horizontal position (see page 43).
- Turn knobs to  position (see page 40).
- Lift infant clear of mattress.

The system waits until at least 250 g (8.8 oz) have been taken off the scale and the scale has been at rest for 3 seconds. Then, tare weight is determined.

- 1 beep sounds.



- Place infant back on the bed.

The system waits until at least 250 g (8.8 oz) have been added to the tare weight and the scale has been at rest for 3 seconds. The infant weight is determined.

- 1 beep sounds.



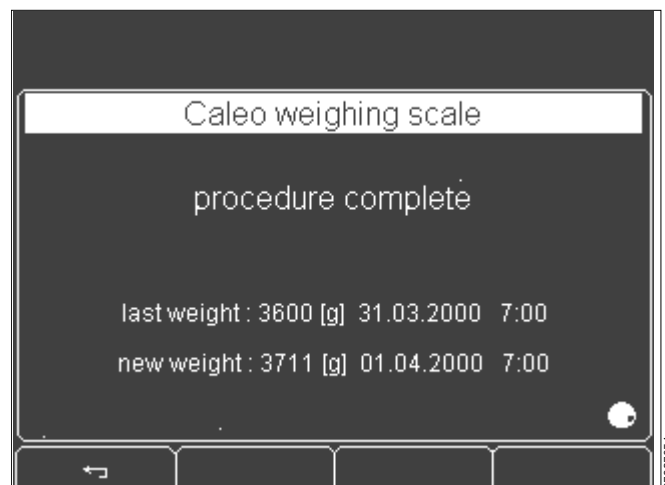
The weighing procedure is complete.

- The current and last weighing results are displayed on screen.

After 30 seconds, the display reverts to the standard screen. or

- Press rotary knob to return to the standard screen.

The screen displays the last weight as advisory text for the next 10 minutes.



Weighing procedure cancelled

The weighing procedure is cancelled if the scale is not unloaded or reloaded within 30 seconds.

- 3 short beeps are emitted.

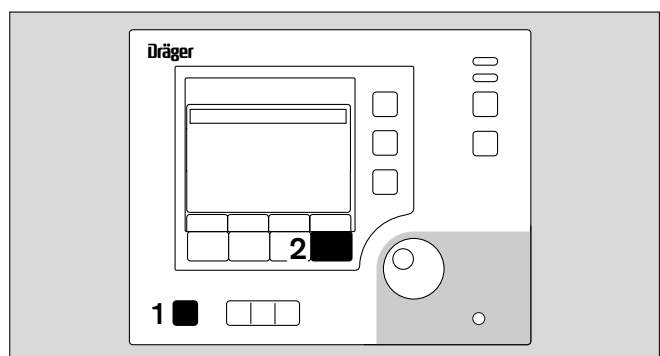
Weighing without tare

If the last tare weight was obtained no longer than 60 minutes earlier and no objects have been placed on or been removed from the bed, a new tare weight does not have to be obtained again.

- 1 To activate the weighing process, press function key

Caleo offers reweighing directly without obtaining a new tare weight.

- 2 Press »reweigh« key to weigh without obtaining a new tare weight.



The system waits until the weighing scale has remained at rest for 3 seconds. Weighing then proceeds.

- 1 beep is emitted.



Operation

End of Operation

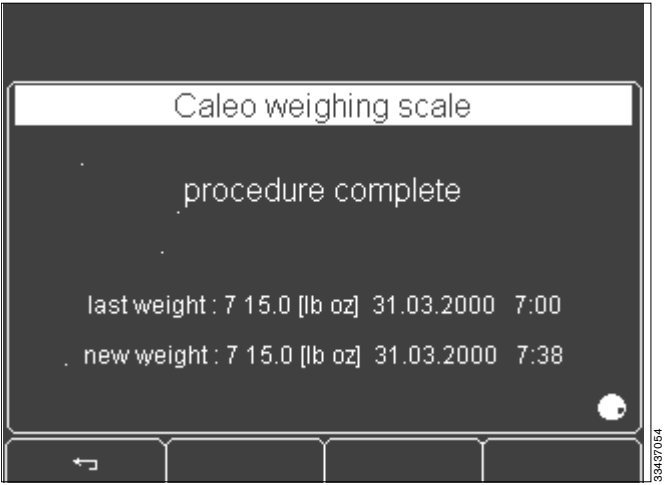
The weighing procedure is complete.

- The present and last weights are displayed.

After 30 seconds, the display returns automatically to the standard screen.

- or
- Press rotary knob to display the standard screen.

The screen displays the last weight as advisory text for the next 10 minutes.

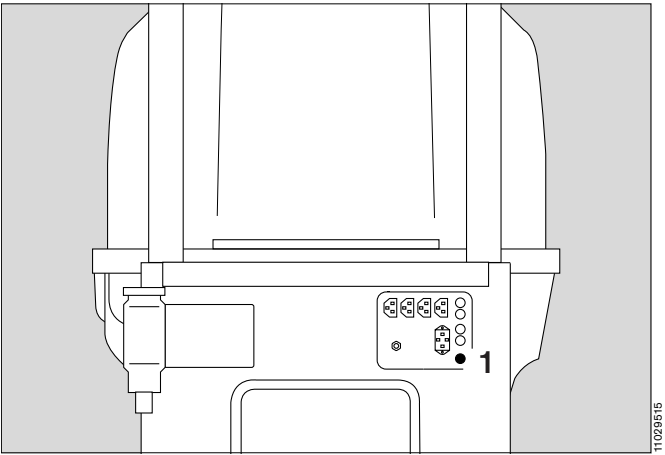


End of Operation

Switch off incubator

- 1 Press on/off switch to switch off the incubator.

The incubator is turned off.



If O2 supply hose is connected:*

Disconnect probe from the outlet of the central O2 supply pipeline and place it in the "standby" position, if available (follow respective Instructions for Use).

* For available O2 option

Care / Maintenance

Contents

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Care

Precautions

The Caleo incubator system must be thoroughly cleaned and disinfected after each patient, and according to approved hospital protocols.

Perform any disinfection procedures according to established hospital procedures as well as to the following additional instructions.

WARNING !

Always follow accepted hospital procedures for handling equipment contaminated with body fluids.

For the cleaning and disinfecting of accessories, refer to their respective operating instructions.

WARNING !

Always disconnect power supply before cleaning and disinfecting.

WARNING !

Risk of burns from heater!

When the incubator is closed, the heater is still hot enough to inflict serious burns for a long time after switching off (70 °C = 158 °F after 1 hour).

The following materials are used for the patient environment:

Components	Material
Canopy, access doors	Polycarbonate
Column/bassinet mount	Thermoformed styrene-butadien
Bassinet	Thermoformed styrene-butadien
Bed	Polystyrene
Mattress Caleo®, standard	Polyurethane
SoftBed™ Caleo®	Polyurethane / polyester

Disinfecting / Cleaning / Sterilizing

CAUTION !

Certain components of the Caleo incubator consist of materials that are sensitive to certain organic solvents sometimes used for cleaning and disinfecting (e.g., alcohols, phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.). Exposure to such substances may cause damage that is not always immediately recognized. Sterilization of the incubator or components with ethylene oxide (EtO) or disinfection with formaldehyde is also not recommended.

To prevent any damage, we recommend that only detergents and disinfectants are used that are compatible with the materials used in the incubator and its components and accessories, e.g. surface disinfectants on the basis of

- aldehydes, or
- quarternary ammonium compounds

for disinfection procedures.

The following surface disinfectants are recommended:

Surface disinfectants	Manufacturer
Dismozon® pur	Bode Chemie GmbH & Co., Germany
Incidur®	Henkel-Ecolab Deutschland GmbH
Trichlorol	Lysoform, Germany
Virkon	Tetenal, Germany
Bacillol 25	Bode Chemie GmbH & Co
Seculyse	Paragerm (Henkel Ecolab), France
Sekupoudre	Paragerm (Henkel Ecolab), France
Vaposeptol	Paragerm (Henkel Ecolab), France
Cidex	Johnson & Johnson, Taiwan
Habitane	Zeneca Limited, Norway
Kloramin	Norsk Medisinal Depot A/S, Norway
Sactiv	Diversey Lever, Finland
Viraclean	Whiteley, Australia

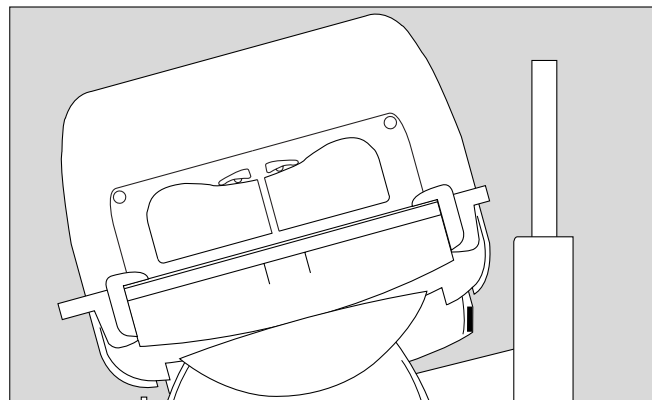
Ensure that all disinfectants are registered with the U.S. Environmental Protection Agency for use as intended. Always follow the instruction labels specifically with respect to prescribed concentrations and the necessary exposure times.

Disassembly

Checking the air intake filter

To make the filter easier to remove, set incubator to a tilted position.

- Connect to line power.
- Press on/off switch until it clicks into position to switch the incubator on.
- Tilt the bed (see page 43).

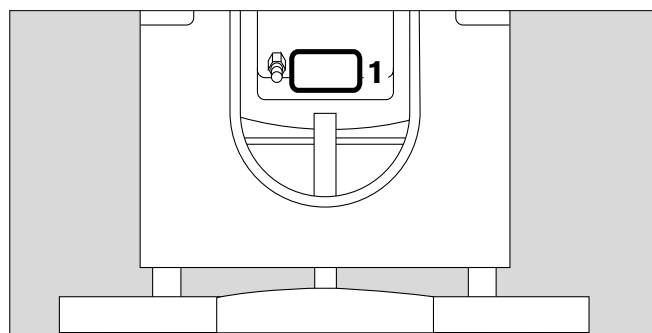


- 1 Pull air intake filter unit downwards and out of the unit.

- Check expiration date marked on the label on the filter frame.

If filter appears dirty or damaged, or the expiration date is reached:

- Separate filter frame and filter holder at the snap-on fitting and replace old filter with a new one.
- Mark label of the new filter with the expiration date (2 months after installation), and affix label to the filter frame.



Removing the water supply

- Close clamp on the water transfer set.
- Remove the water bag and water transfer set and dispose of properly.

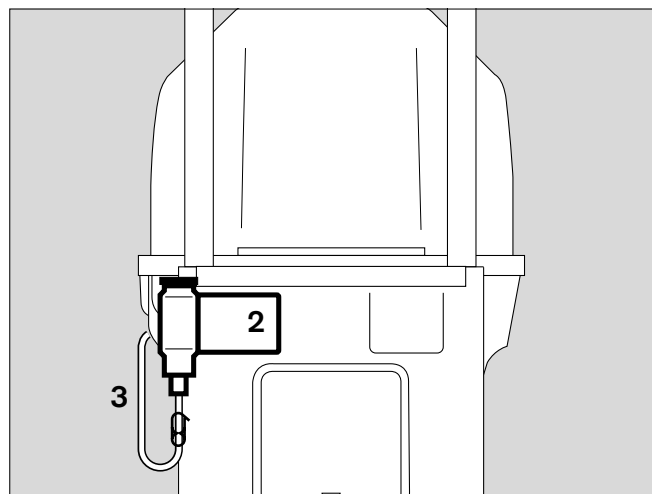
Or:

- 2 Remove water container from its holder.
 - 3 Detach water transfer set from the water container and water connection tube.
- Dispose of the water transfer set.

- Either clean the water container in a parts washer at 93 °C (200 °F) with 10 min. dwell time,

or

- sterilize at 134 °C (273 °F)*.

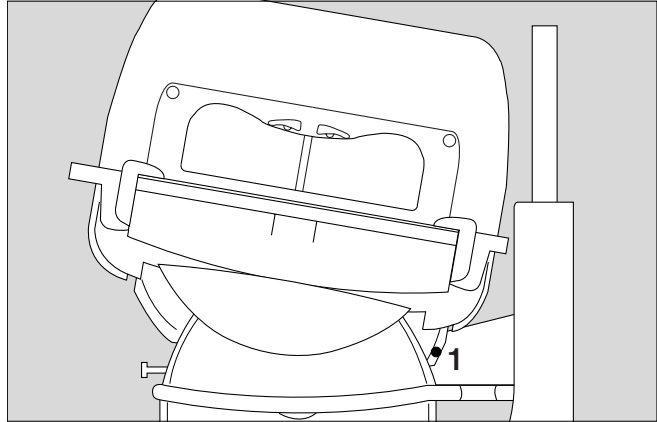


* Observe national and international standards regarding procedures for cleaning, disinfection, and sterilization.

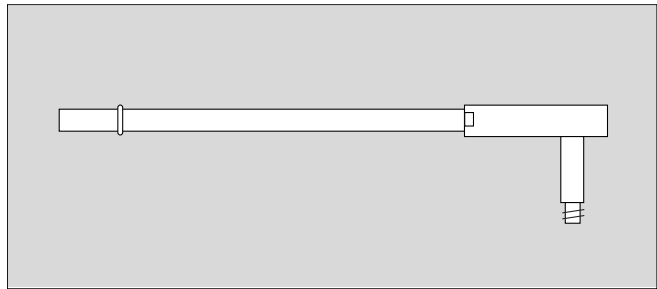
Removing the water connection pipe

- Tilt incubator to make the water connection pipe and air intake filter easier to remove (see page 43).

- 1 Turn water connection pipe 90° clockwise and pull it out of its guide channel.



- Clean the water connection pipe in a parts washer at 93 °C (200 °F)*.
- or
- sterilize at 134 °C (273 °F)*.



- Tilt Caleo bassinet back to the horizontal position (see page 43).
- Switch on cleaning mode** (see page 92).

After cleaning mode** is complete or if cleaning mode is not provided:

- Switch off incubator. Disconnect from line power and disconnect the medical gas supply.

WARNING !

Always disconnect all supplies before disassembly.

- Remove any auxiliary equipment installed (for care instructions see the particular Instructions for Use of the respective equipment).

WARNING !

**Risk of burns upon contact with the heater.
Allow Caleo to cool down before further disassembly.**

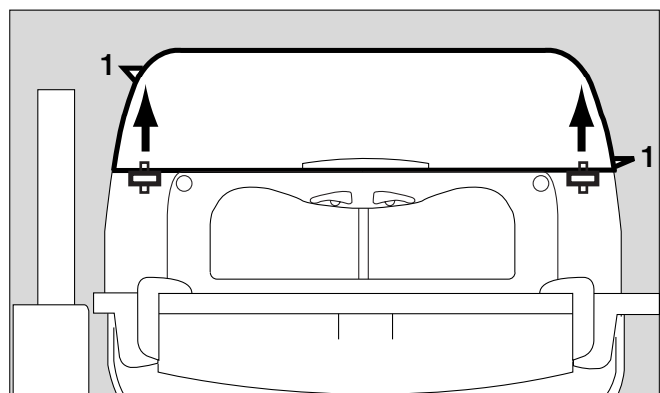
* Observe national and international standards regarding procedures for cleaning, disinfection, and sterilization.

** Available option

Remove canopy:

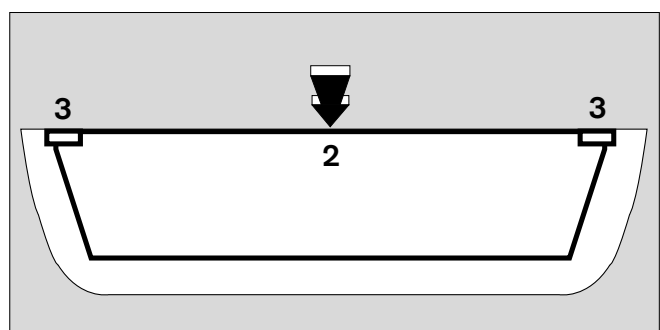
1 Grasp handles on sides of canopy with both hands. Keeping canopy level, lift it vertically off its supports.

- Remove obvious soiling with a disposable cloth and detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



To remove the double wall:

- Remove canopy and lay it upside down (onto a soft, non-abrasive surface).
- 2 Squeeze double wall inwards slightly, and
- 3 release holes in the double wall from the retaining clamps in the canopy.
- Pull double wall out of the canopy.

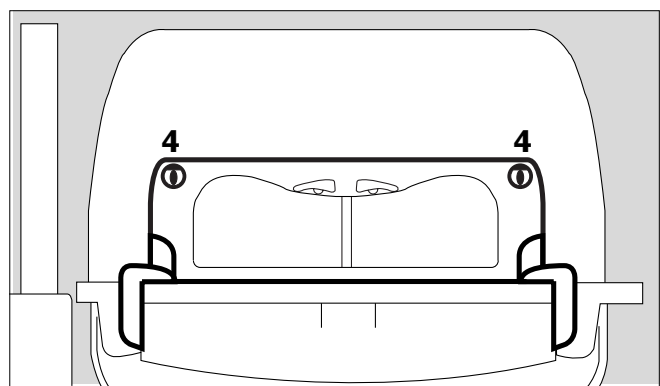


- Remove obvious soiling with a disposable cloth and detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.

Open front doors:

4 Turn the two locking knobs inwards as far as they will go and fold down the front door.

- Fold out the hinged double walls to clean them.
- Open the side doors in the same way.
- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



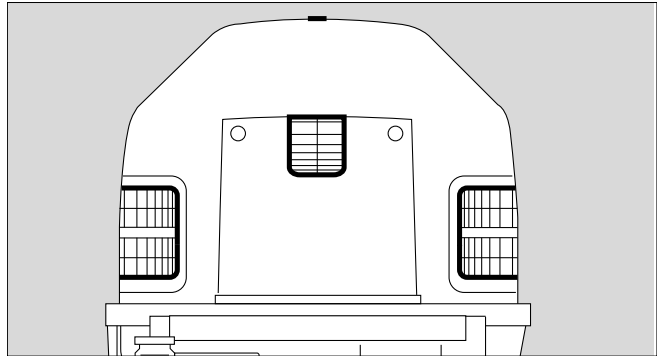
Care

Disassembly

- Remove all U-grommets and access port seals.
- Clean parts in a parts washer at 93 °C (200 °F)*.

CAUTION !

U-grommets cannot be autoclaved at 134 °C (273 °F).

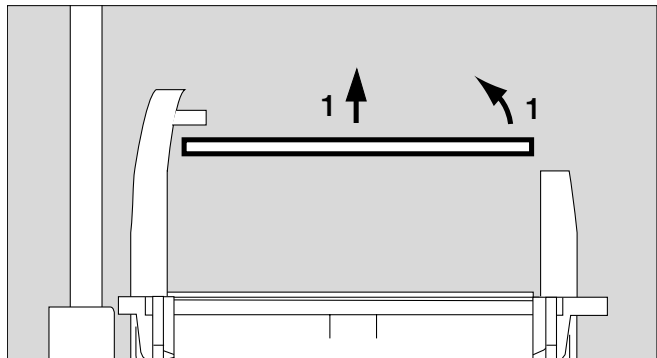


- Remove mattress from bed.

1 Remove bed.

CAUTION !

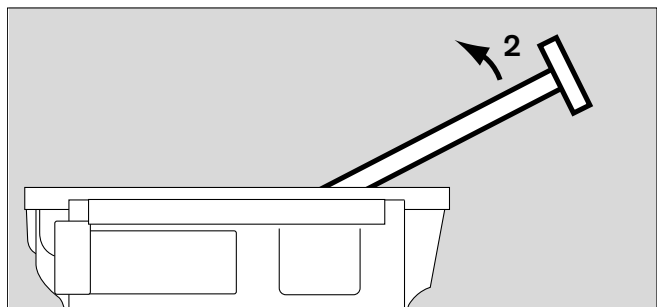
Take care not to damage the sensor unit when removing patient bed.



- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.

Remove x-ray drawer:

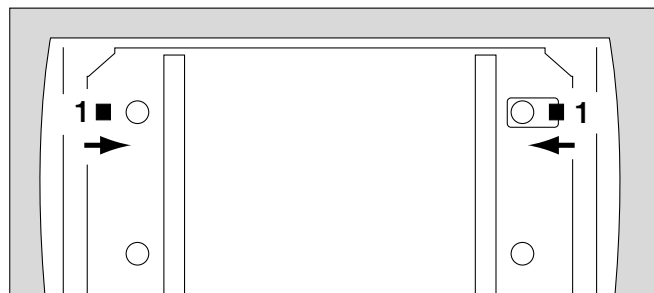
- Using the recessed handle, pull x-ray drawer out as far as it will go.
- #### 2 Tilt drawer upwards and pull it out of the unit.
- Remove visible soiling with a disposable cloth and detergent.
 - Wipe-disinfect all surfaces.
 - After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



* Observe national and international standards regarding procedures for cleaning, disinfection, and sterilization.

Remove trough:

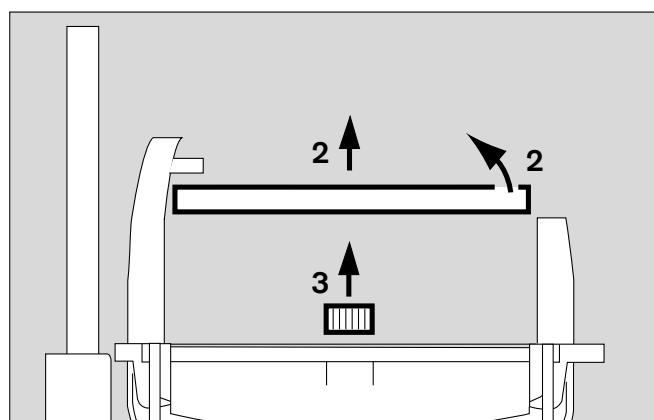
- 1 Press both catches inwards and pull the trough upwards.



- 2 Lift trough out.

- 3 Remove fan.

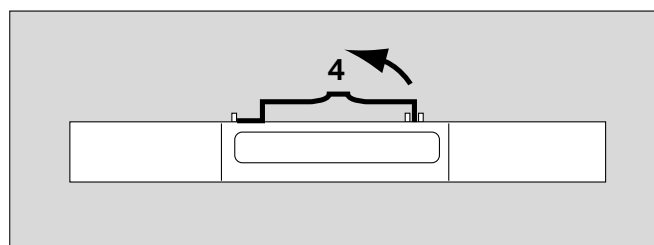
- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



- Turn trough over.

- 4 Lift air guide plate to the side to disinfect and clean.

- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect the surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



Care

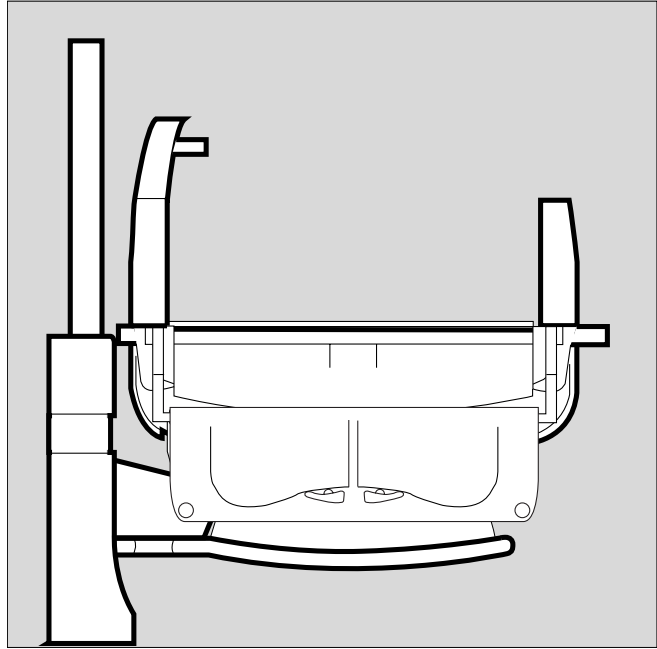
Disassembly

Chassis/incubator body

- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect the surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.
- Remove any dirt near the openings of the sensor unit.

CAUTION !

Do not allow any moisture to enter the sensor unit.
Do not disinfect control panel by immersion or spraying.
Sensor damage may result.

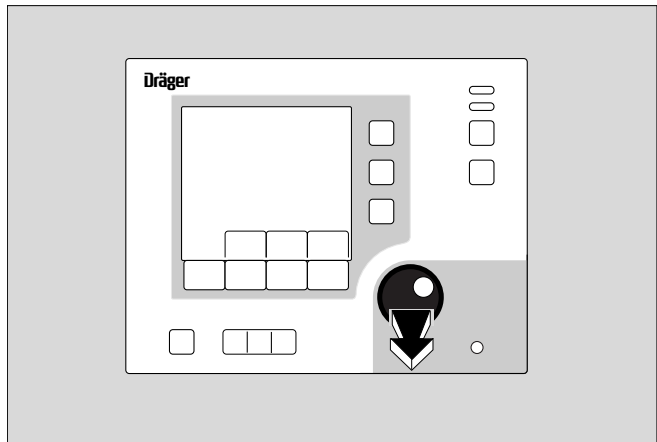


Control panel

- Pull rotary knob from the control panel.
- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect the surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.

CAUTION !

Do not allow any moisture to enter the control panel.
Do not disinfect control panel by immersion or spraying.
Equipment damage may result.



CAUTION !

Ensure that only recommended cleaning agents and disinfectants are used!
The acrylic and Makrolon material may develop stress cracks if other agents, such as alcohol, are used.
Do not use UV radiation on the incubator. This also may cause cracks in the acrylic parts.

Before Reusing With a Patient

- Check that the system has been cleaned and disinfected in conformity with all applicable hospital protocols.
- Reassemble the equipment with disinfected hands.
- Reassemble all equipment and re-install accessories, see "Disassembly", page 109.

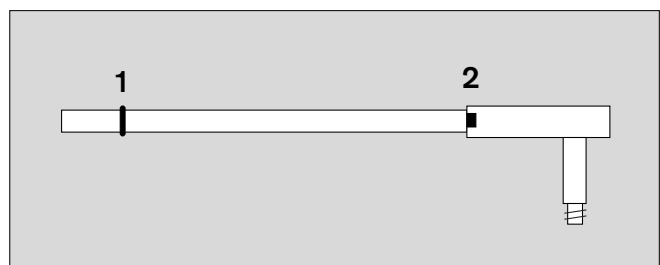
NOTE: When inserting the trough, make sure that both latches snap in place.

If the holders of the trough are damaged:

- Take unit out of service.

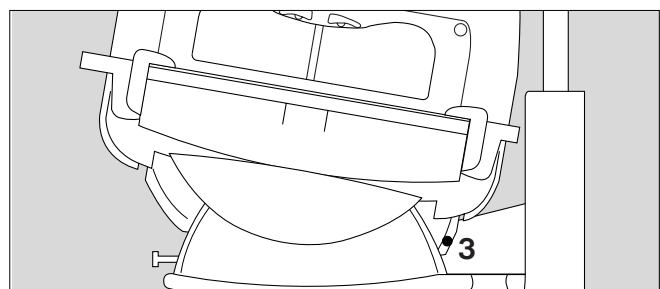
Installing the water connection pipe:

- 1 Check O-ring (2M 50 346) for damage and replace if necessary.
- 2 Check pin for damage.

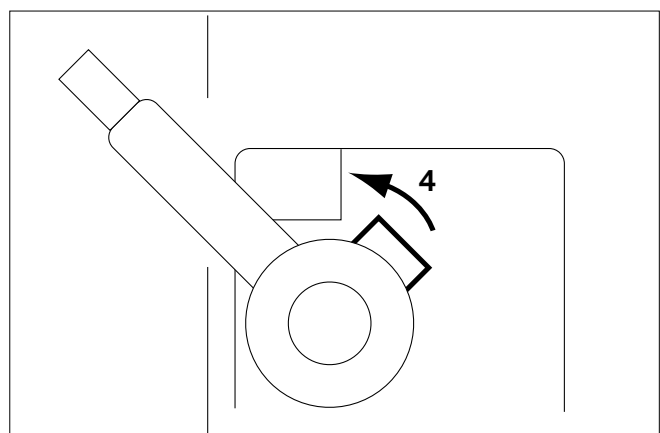


To make water connection pipe easier to install, first tilt incubator.

- Connect the incubator to line power.
 - To switch incubator on, press on/off switch until it clicks into position (see page 56).
 - Tilt the bed (see page 43).
- 3 Push water connection pipe into the guide channel, holding the luer lock connection vertically at the top.



- After overcoming a spring force,
- 4 Turn water connection pipe 90° counterclockwise and secure pin in its holder.



- Check that the incubator is ready for operation – Refer to the checks below and to "Before Each Use", page 46.

WARNING !

The incubator is ready for operation only when all checks have been carried out successfully.

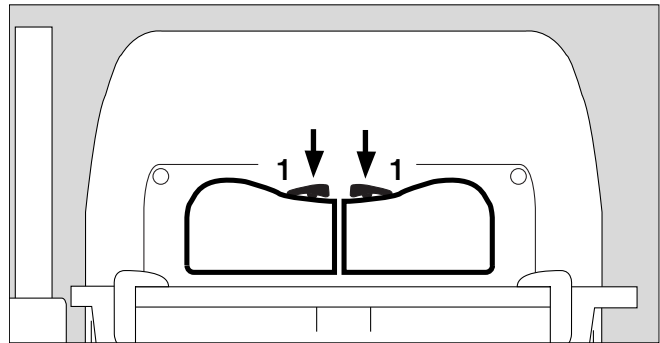
Check that hand ports latch securely

- Perform this test on all 4 hand ports

- 1 Press catch to open hand port.
- Close hand port until latch engages twice.
 - Pull edge of hand port – it must not open.

If hand port latches do not remain properly engaged:

- Take unit out of service.



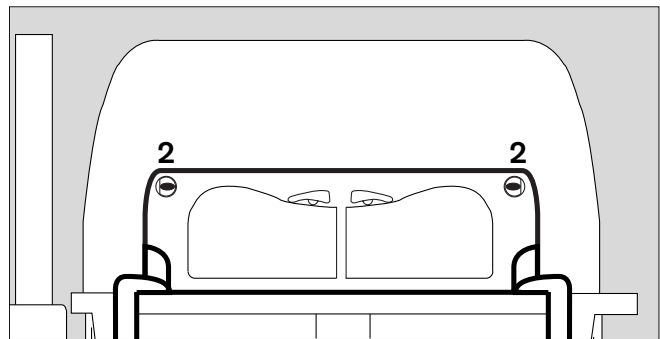
Check that large access doors latches securely

- Perform this test on both doors

- Open door slightly.
- 2 Then, push door back into its closed position. Turn the two knobs outwards until they engage in the horizontal position.

WARNING !

Always ensure that both knobs of the access doors are engaged in position in order to avoid any risk of an infant falling out of an incubator. The red catch behind each knob must no longer be visible!



If the front door fails to remain engaged or if the red catch remains visible:

- Take unit out of service.

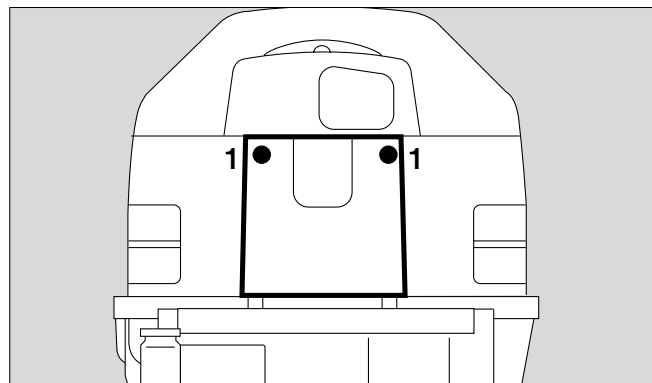
Check that the side door latches securely

- Perform this test on both side doors

- Open side door slightly.
- 1 Then, push door back into its closed position. Turn the two knobs outwards until they tangibly engage in the horizontal position.

WARNING !

Always ensure that both knobs of the side doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.
The red catch behind each knob must no longer be visible!

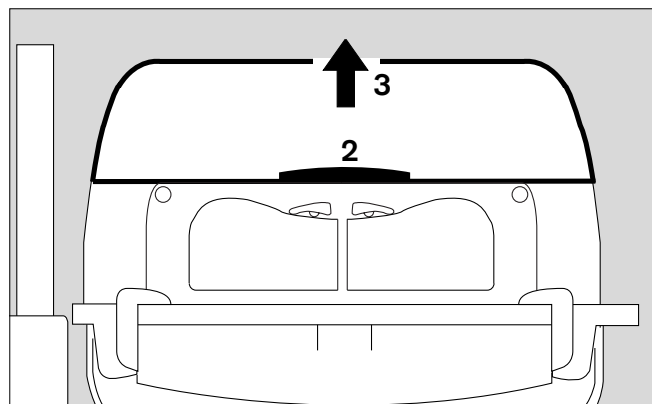


If the side door fails to remain engaged or if the red catch remains visible:

- Take unit out of service.

Check that the canopy is securely seated

- 2 Grasp handle and open canopy.
- 3 Tilt canopy back (approx. 60°).

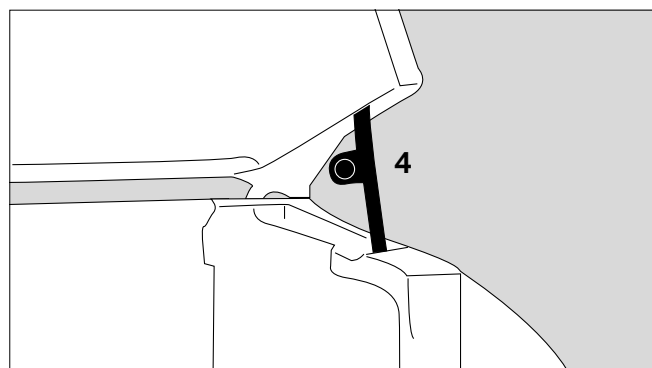


Check all four corners of the canopy for any damage to the hinge.

- Tilt canopy up slightly, and
 - 4 check canopy prop.
 - Lower canopy back.
- Perform check from both sides.

If canopy does not open and close properly:

- Take unit out of service.



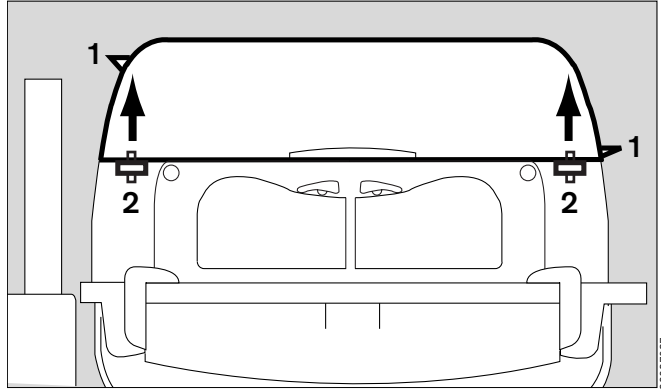
Care

Before Reusing With a Patient

- 1 Grasp handles on the sides of the canopy with both hands.
- 2 Lift canopy horizontally off the side windows.

If the canopy holders are damaged:

- Take unit out of service.

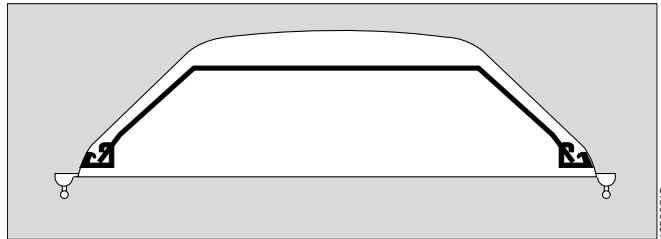


Check that the double wall is securely in place

- All 4 retaining clamps in the canopy must be seated in the holes of the double wall.

If the double wall or the retaining clamps in the canopy appear damaged:

- Take unit out of service.

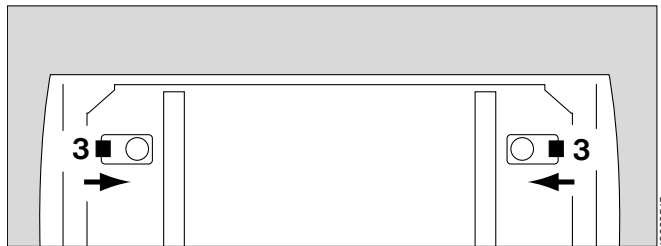


Check that trough is securely seated



- Remove canopy.
- Remove mattress.
- Remove bed.
- 3 Check catches for trough.
- Place bed on trough.
- Place mattress on bed.
- Re-install canopy.

If catches for the trough appear damaged:

- Take unit out of service.



Slide the bed out

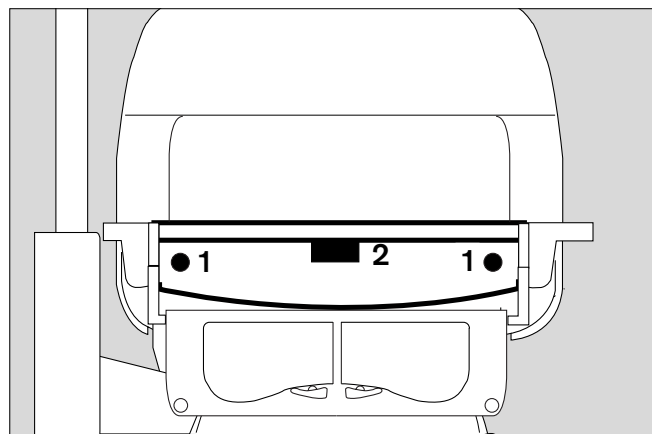
- Open front door and fold it down.
- 1 Set the two knobs to the  position,
- 2 Grasp bed by the recessed handle or by the knobs and pull it out towards the front as far as it will go.
- 2 Push bed back until it clicks into place,
- 1 Turn knobs to the  position.
- Close front door.

If the bed cannot be pulled out or pushed in or if the knobs are damaged:

- Take unit out of service.

WARNING !

**Always ensure that the bed is pushed all the way in!
Otherwise the ducted flow of warm air will be interrupted,
and the infant may be warmed or cooled excessively.**



To remove possible disinfectant residues, we recommend running the incubator in standby mode.

- Switch on Caleo (see page 56).
- Activate air temperature control (see page 57).
- Run Caleo at 37 °C with opened access ports.

If using a water container:

Do not refill the water container until just before placing a new infant in the incubator (see page 44)!

If using a water bag:

Do not connect the water bag until just before placing a new infant in the incubator (see page 44)!

Care List

What Reusable components	How often Care intervals	How		
		Disinfect and clean Wipe ¹	Cleaning and disinfecting machine (parts washer) ² 93 °C (200 °F) ³	Sterilize Steam 134 °C (273 °F) ³
Connection tube	Replace weekly and with each change of patient			
Water container	Change of patient/weekly		yes	yes
Water connection pipe	Change of patient/weekly		yes	yes
Canopy	Change of patient/weekly	yes		
Double wall	Change of patient/weekly	yes		
Front door	Change of patient/weekly	yes		
Side doors	Change of patient/weekly	yes		
Double walls	Change of patient/weekly	yes		
U-grommets, seals	Change of patient/weekly		yes	
Mattress	Change of patient/weekly	yes		
X-ray drawer	Change of patient/weekly	yes		
Trough	Change of patient/weekly	yes		
Fan bracket	Change of patient/weekly	yes		
Fan impeller	Change of patient/weekly	yes		
Chassis	Change of patient/weekly	yes		
Control panel	Change of patient/weekly	yes		
Rotary knob (control panel)	Change of patient/weekly	yes		
Air intake filter	Replace every 2 months			

1) Use surface disinfectants based on aldehydes and quaternary ammonium compounds

2) Use detergent only. Do not use disinfectants that release alkali or chlorine. Risk of corrosion!

3) Observe national and international standards regarding procedures for cleaning, disinfection, and sterilization.

Maintenance

WARNING !

To avoid any risk of infection, clean and disinfect incubator and accessories before any maintenance according to established hospital procedures – this applies also when returning units or parts for repair.

WARNING !

Never operate the Caleo incubator if it has suffered physical damage or does not seem to operate properly. We recommend that you contact DraegerService for maintenance service for the Caleo incubator.

WARNING !

In order to avoid risk of electric shock, always disconnect power supply before starting any maintenance procedures.

CAUTION !

The device must be inspected and serviced at regular 1 year intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with DraegerService through your vendor.

For repairs of the Caleo incubators we recommend that you contact DraegerService.

Replacement of Parts/Maintenance Intervals

Replaceable parts	Intervals						Who?
	when necessary	weekly	every 2 months	every 6 months	once a year	every 2 years	
Fresh air filter			X				Medical and technical personnel
Grommets, seals, etc.	X ¹						Medical and technical personnel
O-ring, for water connection pipe	X						Medical and technical personnel
Fan motor						X ²	Authorized technicians
Lithium battery						X	Technicians
Skin temperature sensors		X ³					Medical personnel
Adhesive pads		X ⁴					Medical personnel
Foam mattress	X						Medical personnel
Maintenance							
Preventive maintenance					X		Authorized technicians
Calibration							
O ₂ sensors					X		Authorized technicians

- 1) Replace if the material becomes brittle or sticky or if strips of material have become detached
- 2) Exchange after 18,000 to 20,000 hours of operation
- 3) At the latest when changing patient
- 4) At the latest when changing patient

Disposal

Disposal of the water transfer set and air intake filter

- with household waste.

Disposal of O₂ sensors and batteries

WARNING !

Treatment of batteries and O₂ sensors

- Do not throw into fire! Risk of explosion.
- Do not force open! Cells contain corrosive acid that may cause caustic burns.
- Do not attempt to recharge battery. Risk of explosion.

CAUTION !

For disposal of batteries and O₂ sensors follow all local, state, and federal legislations with respect to environmental protection.

Information can be obtained from local environmental and public health authorities or from approved waste disposal companies.

Disposal of the incubator

At the end of its service life:

- dispose of the incubator in accordance with local, state, and federal waste disposal regulations
- or
- send incubator to an approved waste disposal company for disposal.

Further information can be obtained from local environmental and public health authorities.

NOTE: The material of all plastic parts weighing more than 50 g (1.7 oz) are marked with their material code so that they can be disposed of/recycled in an environmentally compatible fashion.

Troubleshooting

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Troubleshooting

Troubleshooting – Error Messages

All error messages are displayed on screen. They are listed below in **alphabetical** order.
See also "Alarm Description", page 143.

Message	Cause	Remedy	Audible alarm silence
Air heater inoperable Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty air heater.	Take unit out of service.	1 min
Air temp. deviation above 1.5 °C (see "Configuration", page 95) Measured value starts flashing on screen. Yellow alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Specified alarm threshold for deviations from the setpoint has been exceeded.	Reduce/increase humidity. Close canopy, front door, and hand ports. Check setpoint. Check configuration (page 95).	15 min
Air temp. sensor inoperable Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty air temperature sensors.	Take unit out of service.	1 min
Air temperature too high Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Incubator temperature above 38 °C Incubator temperature above 40 °C ¹ ¹⁾ applies when operated in extended setpoint range	Remove external heat sources. Take unit out of service.	5 min
Battery discharged Yellow alarm LED on the control panel starts blinking.	Discharged battery.	Connect incubator to line power for about 30 minutes. ² ²⁾ System date and time for trend data may be wrong. Set date and time in configuration menu (page 96).	1 min
Connect skin 1 sensor Three dashes flashing on screen in place of the measured value. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Probe for skin temperature (yellow) not connected.	Check connection and correct if necessary.	5 min

* If not disabled in the configuration system settings, page 97

Message	Cause	Remedy	Audible alarm silence
Fan inoperable Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps)	Faulty fan.	Check fan impeller. Take unit out of service.	5 min
Heater temp. sensor inoperable Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty air heater temperature sensors.	Take unit out of service.	1 min
Humidifier inoperable Measured value of humidity control sytem flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty water heater.	Switch off humidity module. Take unit out of service.	1 min
Humidity deviation above 10 % Yellow LED lights up on the control unit.	Canopy, doors, or hand ports are open. Sensor faulty.	Close canopy, front door, or hand ports. Check connection of water supply. Take unit out of service.	15 min
Humidity sensor inoperable Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm is sounded (5 beeps).	Faulty humidity sensor.	Switch off humidity module. Take unit out of service.	1 min
Key pad locked Intermittent audible alarm sounds (3 beeps) when a key is pressed.	Key functions (setpoint input/ weighing/ menu key) disabled	Activate keypad functions (page 101).	–
Oxygen concentration below 18 %	O2 concentration less than 18 vol. %	Check that the correct gas is connected. Take unit out of service.	1 min
Oxygen deviation above 5 % (can be set between 3 and 5 % – see "Configuration", page 95) Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Deviation of measured O2 concentration from setpoint greater than 3 or 5 %, respectively.	Close canopy, front door, and hand ports. Check O2 connection. Check O2 supply via central medical gas pipeline or O2 cylinder. Check configuration (page 95). Take unit out of service.	2 min

* If not disabled in the configuration system settings, page 97

Message	Cause	Remedy	Audible alarm silence
Oxygen module inoperable Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty O2 module controller.	Switch off oxygen module. Take unit out of service.	1 min
Oxygen sensor deviation above 3 % Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Sensor 1 or sensor 2 faulty.	Switch off oxygen module. Take unit out of service.	1 min
Oxygen sensor 1 inoperable Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps)	Faulty sensor for oxygen measurement. Sensor 1 faulty.	Switch off oxygen module. Take unit out of service.	1 min
Oxygen sensor 2 inoperable Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty sensor for oxygen measurement. Sensor 2 faulty.	Switch off oxygen module. Take unit out of service.	1 min
Skin 1 less than 0.5 °C above skin 2 (see "Configuration", page 98) The measured values for skin temperatures flashing on-screen. Yellow alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Kangaroo Mode alarm: Temperature difference between the central skin temperature (yellow) and peripheral temperature (white) too low.	Check infant's heat exchange. Check configuration (page 95).	15 min
Skin 1 temp. deviation above 0.5 °C (can be set between 0.3 and 1.0 °C – see "Configuration", page 95) Measured value starts flashing on screen. Yellow alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	The specified threshold for deviations from the setpoint has been exceeded.	Check that sensor is correctly attached to the infant. Close canopy, front door, or hand ports. Switch off external heat sources. Remove double walls. Change configuration (page 95).	5 min

* If not disabled in the configuration system settings, page 97

Message	Cause	Remedy	Audible alarm silence
Skin 1 temperature above 39 °C Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Central skin temperature too high.	Check that sensor is correctly attached to the infant. Switch off external heat sources. Check whether double walls can be removed.	2 min
Skin 1 more than 4.0 °C above skin 2 (see "Configuration", page 98) Measured values for skin temperatures flash on-screen. Yellow alarm LED on the control panel start blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Kangaroo Mode alarm: temperature difference between the skin temperature (yellow) and peripheral temperature (white) too high.	Check infant's heat balance. Check configuration (page 95).	15 min
Skin 1 temperature below 36.0 °C (see "Configuration", page 98) Measured value starts flashing on screen. Yellow alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Kangaroo Mode alarm: Skin temperature is falling below the alarm limit.	Increase heat supply to the infant. Check configuration.	15 min
Skin 1 sensor fault Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Sensor 1 for skin temperature (tummy) measurement faulty.	Replace sensor.	5 min
Skin 2 sensor fault Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Sensor 2 for peripheral skin temperature (toe) measurement faulty.	Replace sensor.	5 min
Skin 2 temperature below 34.0 °C (see "Configuration", page 98). Measured value starts flashing on screen. Yellow alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Kangaroo Mode alarm: Peripheral skin temperature falling below the alarm limit.	Increase heat supplied to the infant. Check configuration.	15 min


* If not disabled in the configuration system settings, page 97

Message	Cause	Remedy	Audible alarm silence
Skin 2 temperature above 39 °C Measured value starts flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Peripheral skin temperature too high.	Check that sensor is correctly attached to the infant. Switch off external heat sources. Check whether double walls should be removed.	2 min
Water empty, please refill Measured value starts flashing on screen. Yellow alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Water supply is empty.	Refill water container. Replace water bag.	15 min
Wrong oxygen sensor 2 Message flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Wrong sensor in O2 module. No measurement can be performed with the replacement oxygen sensor.	Take unit out of service. Switch off O2 control.	1 min
Wrong oxygen sensor 1 Message flashing on screen. Red alarm LED on the control panel starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Wrong sensor in O2 module. No measurement can be performed with the replacement oxygen sensor.	Take unit out of service. Switch off O2 control.	1 min

* If not disabled in the configuration system settings, page 97

Troubleshooting – Faults

All faults are listed in the table below in **alphabetical** order. See also "Alarm Description", page 143.

Fault	Likely Causes	Remedy
Bassinet cannot be set to the tilted position.	Motor overheating. Motor faulty.	Wait for 2 minutes. Take unit out of service.
Height adjustment does not switch off.	Switch faulty or loose contact. Motor faulty.	Take unit out of service.
Height adjustment not possible.	Motor for height adjustment overheating. Motor for height adjustment faulty.	Wait for 2 minutes. Take unit out of service.
Red alarm LED on control panel is lit. Continuous audible alarm tone. Audible alarm cannot be silenced.	Serious device fault.	Take unit out of service.
Red LED at  symbol flashing, intermittent alarm tone.	Power failure alarm.	Check power supply. – Connect to line power. Take unit out of service.
Short beep signal (3X) is sounded.	While setting a set value, the rotary knob is not pressed within 20 seconds.	Press rotary knob or cancel input.
The yellow LED in the alarm button is lit.	Alarm suppression is active.	Deactivate alarm suppression.

If any other faults not listed in the table occur, or in case Caleo does not respond as expected: Take unit out of service.

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Theory of Operation

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Theory of Operation

Operating Principle

Inside the Caleo patient "capsule" (Caleo® CalmCapsule™), premature and sick infants are supplied with a controlled amount of heat and, if necessary, humidity* and oxygen*. The user/operator can adjust the incubator climate to suit the needs of the infant, by adjusting air temperature, relative humidity* and oxygen content*. Since the patient capsule acts as a specially protected zone for the infant, the ambient air is filtered before it enters the interior of the incubator.

Accessibility

Caleo provides excellent accessibility to the infant for all regular and intensive care activities: for this purpose, the four hand ports are designed with especially large dimensions (Caleo® JumboPorts™).

The two large access doors can be completely folded down. In addition, two smaller side doors at the head and foot ends of the patient bed can be folded down. If necessary, the hood canopy can also be propped up from two different sides or can be fully removed in an emergency – in order to provide free accessibility to the infant from above.

A total of ten generously dimensioned access grommets ensure clear organization and routing of hoses and cables into the incubator. Each corner features two such grommets, which can be easily removed, especially during "kangaroo care" (when the infant rests in direct skin contact on the mother's or father's chest). This ensures easily manageable cable and hose routing even when the infant is outside the patient capsule. Two additional large tubing ports are located in the side doors at the head and foot end. In addition, the hood canopy contains a hole, e.g. for feeding the infant. The four U-grommets in each corner segment of the incubator hood allow HFV tubing to be inserted, therefore allowing the treatment of infants with a high frequency ventilator while in the incubator without compromising the microenvironment (temperature, humidity, oxygen, noise level).

Bed and Mattress

The bed is especially wide in order to provide sufficient space for the infant under a variety of conditions – such as installation of hoses, when using supports and storage aids, when treating twins in a single incubator and also when turning the infant, e.g. for reintubation in the incubator. The infant lies on a foil encapsulated foam mattress providing easy cleaning and excellent thermal insulation.

* Available option

As alternative, an extra-soft mattress can be used (SoftBed® Caleo®, part no. MX 17 012) to prevent decubitus even more effectively.

The bed can be pulled out when the front door is open. The bed electrically tilts in order to obtain either a head-up (Trendelenburg) or head-down (reverse Trendelenburg) position ($\pm 13^\circ$).

Twins in the Caleo (Caleo® Twincubator™)

Twins can be placed together in Caleo if there are no medical objections and if their total combined weight does not exceed 5 kg. When treating twins in a single incubator, Caleo must be operated in air control mode.

The treatment of twins together in a single incubator may help to prevent post-natal separation trauma. Direct skin contact between the twins can have positive effects on the development of the infants similar to those associated with "Kangaroo" Mode (see page 138). If necessary, the incubator air temperature may have to be reduced, because the infants mutually warm each other by direct contact and would therefore become overheated.

During operation in air temperature mode, skin temperature of the first infant can be monitored with the yellow temperature sensor, while the second temperature channel (white probe) can be used to monitor skin temperature of the second infant.

Possible dangers from the treatment of twins in a single incubator result, e.g. in the case of infections, from the risk of cross-infection, or from possible confusion between the two patients when administering medicines or foods. Also, if the twins require different ambient temperatures or an ambient air with different oxygen or humidity saturation levels, they should be placed in two separate incubators.

X-Raying

The infant may be x-rayed inside the incubator without having to be removed or lifted using the x-ray drawer, which is accessible from outside the incubator. The x-ray drawer can be pulled out without having to open the Caleo front door. Unnecessary disturbance of the infant is therefore avoided. A grid is provided on the x-ray drawer to help align x-ray cassettes.

* see Caleo list of accessories.

Integrated Infant Scale*

With the optional, fully integrated incubator infant scale, patient weight can be determined without having to remove the infant from the protective climate of the incubator. Even with the built-in scale, the use of the x-ray drawer remains possible. In order to be weighed, the infant must be lifted once in order to reset the scale to zero (tare weight). The infant can then be placed back on the mattress. The current and previous weights are displayed for information. The results of the last 30 weighings can be graphically represented in the trend display.

Weighing without lifting the infant again (i.e. without obtaining a new tare weight) is possible. This option is useful when the weight has to be taken again for verification purposes shortly after the first weighing, or if, e.g. the weight with full and empty diaper needs to be determined. The entire weighing procedure is guided by brief audible signals, so that the operator's full attention can remain with the patient.

When weighing the infant inside an incubator, great care must be taken that no hoses or cables jam the bed or might distort the weight measurement. If possible, all tubing or cables should be lifted together with the infant. When the infant is placed back on the mattress, tubing and cables should still be held slightly raised until the new weight appears on the screen (to ensure that the weight of tubing and cables is not added to the infant weight during the weighing procedure).

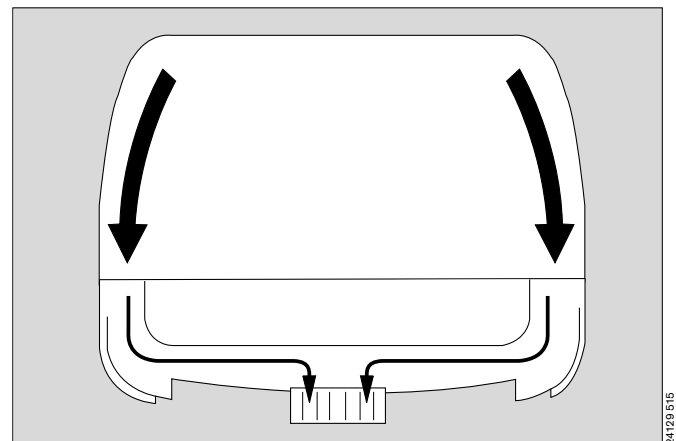
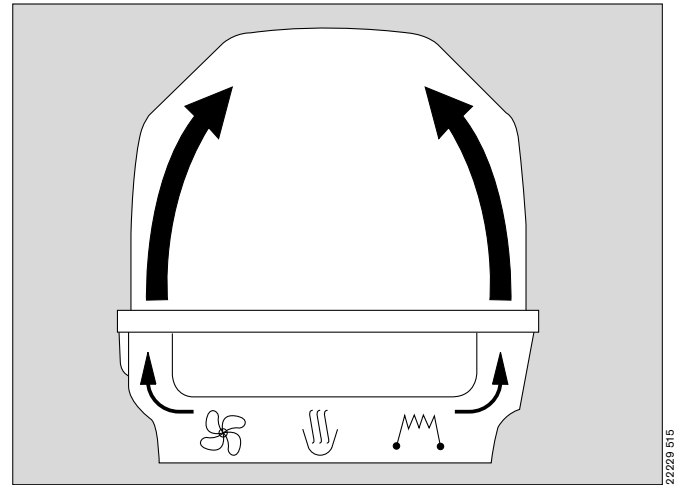
The infant scale in the Caleo comprises four weighing elements located underneath the bed, an electronic measuring and analysis unit and a special page on the control monitor. In normal mode, the entire bed rests on these four weighing elements under the bed. A safety system prevents the weighing elements being damaged if loads of more than 10 kg are applied. When removing the bed, it is first raised slightly by turning two knobs so that it can then be pulled out gently.

* Available option

Airflow

The heated and humidified air flows into the incubator hood from both sides. It is guided up the inside of the front flap, along the hood canopy and then down the two transverse sides by suction. The air from the interior is mixed with fresh ambient air by an air filter and is circulated by a fan. Along this path, the air is channelled past an electrically powered heater and is humidified if necessary*.

The infant lies in a calm zone with low airflow velocity. Convective heat loss is therefore kept to a minimum. When the large access doors or hand ports (Caleo® JumboPorts™), are open, an efficient warm air curtain prevents cooling of the patient capsule.



Air Temperature Control

The user sets the desired air temperature in the patient capsule on the incubator control panel (setpoint for air temperature in air temperature mode). The current air temperature is measured by the air temperature sensor in the patient capsule (at the infant's head end of the incubator) and is then compared to the setpoint. If the set value is greater than the actual measured air temperature, the heater receives the signal to apply more heat. The air temperature inside Caleo therefore increases. If the setpoint is lower than the actual measured air temperature, the heater receives the signal to apply less heat. The air temperature inside Caleo drops. If the current air temperature deviates from the set value by more than $\pm 1.5\text{ }^{\circ}\text{C}^{**}$, an alarm is triggered. The audible signal of this alarm can be muted by the user. As soon as the deviation in the measured air temperature is within $\pm 1.5\text{ }^{\circ}\text{C}^{**}$ of the set value (see above), the alarm is cancelled.

* Available option

** Other configurations possible, see "Configuring alarm settings", page 98.

Caleo temperature control characteristics

The desired temperature increase is achieved rapidly due to the high heating power of Caleo. Lowering air temperature takes longer, due to the good thermal insulation of the incubator.

Note on setting air temperature setpoint for Caleo:

Inside the incubator, the infant has limited

- convective heat loss, because air velocity above the mattress is low.
- conductive heat loss through the mattress, because the foam mattress is well insulated.
- evaporative heat loss, provided that humidity^{*} is set relatively high (above 60 %).
- radiant heat loss, provided that the canopy double wall^{**} is installed.

Skin Temperature Measurement

Two skin temperature sensors can be connected to measure central (tummy) skin temperature (yellow skin temperature sensor) and peripheral temperature (white skin temperature sensor). The measured value of the yellow skin temperature sensor is used to regulate the incubator heater in "skin temperature control mode".

ThermoMonitoring™

The term ThermoMonitoring™ refers to the continuous measurement and display of a central temperature and a peripheral temperature. Instead of the true central (core) temperature, a central (near-core) skin temperature can be used, as it is measured for the incubator's skin temperature control.

The continuous display of the difference between these two temperatures permits early detection of cold stress. However, heat stress, thermoregulation problems, and, e.g., infections can also be more rapidly detected by displaying the two temperature values and evaluating their difference.

Consequently, Caleo provides the possibility of switching between a standard screen with large numeric digits and a trend screen showing trend graphs of a maximum of two temperatures. In this way, the difference between central skin temperature and peripheral skin temperature essential for ThermoMonitoring™ can be displayed continuously.

In addition, trend analysis allows to call up values from the past when looking to explain, in hindsight, the development of disease symptoms or the development of hypothermal stress. Values going back a maximum of seven days can be accessed. In addition, the desired time window can be set (between 3 hours and seven days).

* Available option

** See Caleo accessories

With the "Trend Main Page" option selected from the main menu, the user can preconfigure which trend to display when switching from numerical to trend display.

In addition to showing the two skin temperatures, the display can show air temperature, humidity*, oxygen*, and the weight* from up to 30 weighings.

Skin Temperature Control

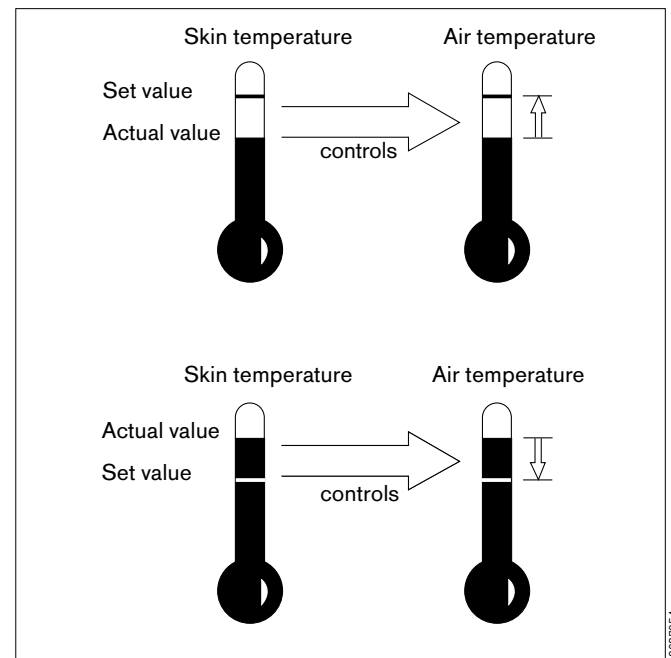
When Caleo is operated in skin temperature mode, this mode can be set on the control unit. At least the yellow skin temperature sensor (Skin 1) must be plugged in and be properly attached to the infant. The user sets the setpoint for skin temperature on the control panel. The infant's actual skin temperature is measured by the yellow skin temperature sensor (Skin 1) and compared with the setpoint.

The difference between setpoint and measured actual value is used to control the air temperature in Caleo between a minimum of 20 °C and a maximum of 39 °C.

If the setpoint is higher than the currently measured skin temperature (skin too cold), the heater receives a signal to supply more heat. The air temperature in Caleo rises, thereby also increasing the infant's skin temperature.

If the setpoint is lower than the actual measured skin temperature (skin too hot), the heater receives a signal to apply less heat. The air temperature inside Caleo drops, thereby also reducing the infant's skin temperature.

The longer the deviation between the set value and the actual measured value persists, the more powerfully heat is supplied by the heater (if the skin is too cold) or the more the air temperature in Caleo is reduced (if the skin is too warm).



Wait for the controller to reach steady state.

The infant's skin temperature varies frequently, e.g. due to food intake or medical care. Deviations of a few tenths of a degree are normal.

Therefore:

Only change the set value of the skin temperature if the intention is to change the infant's (central) temperature.

If the actual skin temperature deviates from set skin temperature by more than ± 0.5 °C**, an audible alarm is triggered.

This audible alarm can be silenced by the user. As soon as the measured value deviates from the set value by less than ± 0.5 °C** (see above), the alarm is deactivated again.

* Available option

** Other configurations possible

Kangaroo Mode

Kangaroo Mode (Caleo® Kangaroo Mode™) simplifies the operation of the incubator when the infant is removed to have direct skin contact with the mother or father ("skin-to-skin care"). This mode provides the user with extended monitoring functions in order to detect infant hyperthermia or hypothermia even when the infant is outside the patient capsule.

Other Caleo features designed to ensure easier removal of the infant from Caleo for "kangarooing":

- removable tubing grommets in the corners of the incubator,
- ability to lower the patient bed down to 80 cm (31.5") (with height adjustment*)
- minimal space requirement of the fold-down access door of the Caleo.

The incubator switches to Kangaroo Mode after pressing the "Menu" key on the control panel. Once Kangaroo Mode is activated, the following functions are automatically activated:

● Switchover to "Standby" mode

Since the infant is no longer inside Caleo during "kangarooing", the infant's skin temperature should no longer be used as a measure for controlling the air temperature inside the incubator. Instead, the incubator should be set up so that when "kangarooing" is concluded and the infant is put back inside Caleo, the incubator will be heated to the same temperature and climate as when the infant was taken out of the incubator. Consequently, during "Standby" mode, the following logic is applied:

If Caleo was previously operated in skin temperature mode, it is switched to air temperature mode for the duration of Kangaroo Mode. The setpoint for air temperature is automatically determined as the average air temperature over the last three minutes. The previous setpoint for skin temperature is stored in buffer memory.

If Caleo was previously operated in air temperature mode, the setting remains unchanged.

● Automatic alarm muting

Since, usually, after switching over to Kangaroo Mode, the door is opened and the infant taken out of the incubator, alarms triggered by opening the doors are no longer meaningful. Consequently, all alarms that would normally be activated by opening the large doors are automatically muted for the next 4 minutes. This applies to the following alarms:

- Air temperature deviation
- Oxygen deviation

* Available option

● Activation of special Kangaroo Mode alarms

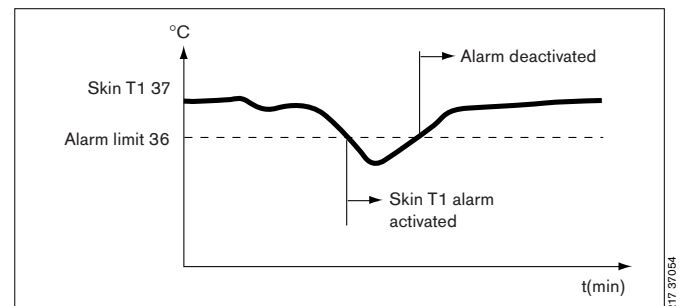
During Kangaroo Mode, the skin (and central) temperature of the infant is frequently found to rise. However, in some cases, the infant becomes cooler. Consequently, the infant's central or skin temperature must be regularly monitored. In order to perform this monitoring with as little nuisance alarms as possible to mother/father and infant, Caleo allows to activate special Kangaroo Mode alarms during operation in Kangaroo Mode. These alarms are set in the configuration. The following alarm limits are set:

- Lower alarm limit for the skin temperature
(Skin 1; T1) = Skin T1 min
- Lower alarm limit for the peripheral temperature
(Skin 2; T2) = Skin T2 min
- Lower alarm limit for the difference
between T1 and T2 = Delta T min
- Upper alarm limit for the difference
between T1 and T2 = Delta T max

These kangaroo alarms have the following significance:

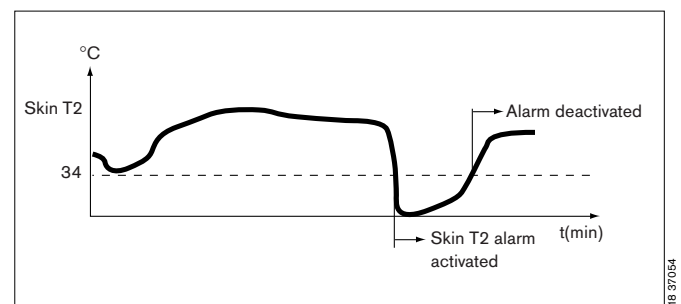
Skin T1 min:

The alarm is triggered as soon as the (central) skin temperature (T1, yellow skin temperature sensor) falls below this alarm threshold.



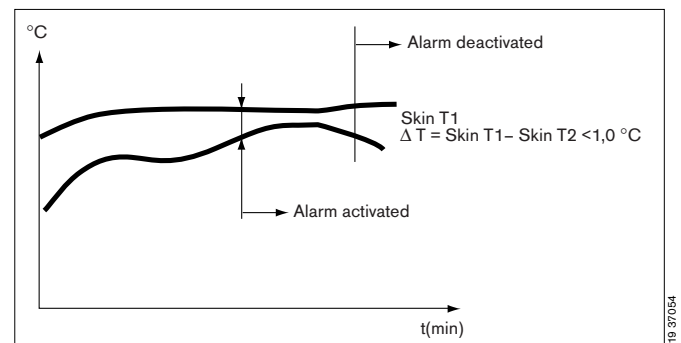
Skin T2 min:

The Skin T2 min alarm is triggered as soon as the peripheral skin temperature (T2, white temperature sensor) falls below this alarm threshold.



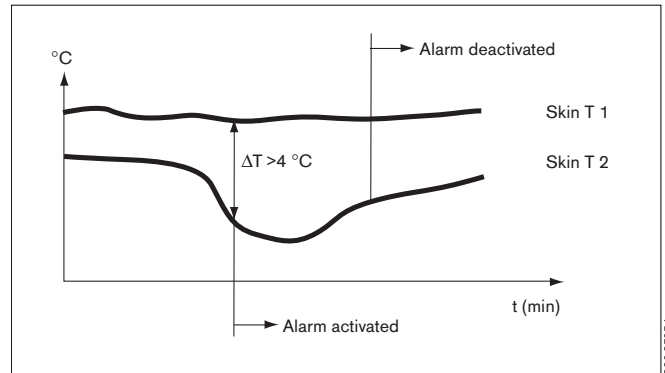
ΔT min:

This alarm is triggered if the difference between Skin T1 and Skin T2 is less than this alarm threshold (risk of hyperthermia).



ΔT max:

This alarm is triggered if the difference between Skin T1 and Skin T2 is greater than this alarm threshold (risk of hypothermia).



Each of these alarms can either be set or switched to "OFF" in advance.

However, immediately after switching over to Kangaroo Mode, automatic alarm muting is active for the first four minutes, which includes all special Kangaroo Mode alarms. This allows the infant time to adapt to the new environment.

O₂ Therapy

With closed-loop oxygen control in the patient capsule, oxygen delivery is metered by a microprocessor controlled valve.

In this fashion, the oxygen is introduced into the air ducting system where it is heated and humidified

Humidity Control*

Caleo provides a means for hygienic humidification of the incubator air* by evaporating (boiling) water from a separate supply (water bag or water reservoir).

With closed-loop humidity control, only the desired relative humidity setpoint is entered, and Caleo then automatically controls the evaporator output of the humidifier to maintain the preset relative humidity in the patient capsule. Caleo allows to control humidity in two different fashions:

- manual adjustment of humidity setpoints,
- or
- automatic humidity control (AUTO humidity).

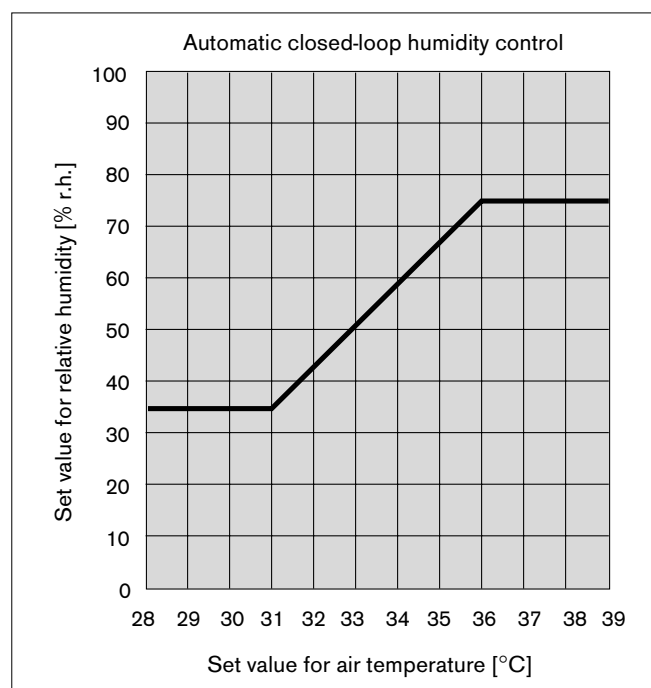
Manual humidity setpoints

A value between 30 % and 99 % relative humidity can be set. The actual humidity level is measured by a humidity sensor in the patient capsule (integrated into the sensor module at the head end of the patient capsule). If the setpoint is higher than the actual measured relative humidity (air too dry), the humidifier receives a signal to allow more water vapor into the patient capsule. Relative humidity inside Caleo therefore rises. If the set value is lower than the actual measured relative humidity (air too humid), the humidifier receives a signal to allow less water vapor into the patient capsule. Relative humidity inside Caleo therefore falls.

AUTO humidity

In closed-loop humidity control, the user can choose between setting relative humidity setpoints manually (see above) and AUTO setting. In AUTO mode, the setpoint for the relative humidity is calculated and set automatically by the system as a function of air temperature (see graph to the right).

This function is based on the observation that small and relatively immature infants require both a higher air temperature and higher relative humidity than larger infants. Consequently, in AUTO mode, the set value for relative humidity is calculated and set as a function of air temperature. The lower the air temperature setting, the lower the set value for relative humidity.



* Available option

Cleaning Mode*

Cleaning mode is only provided if Caleo is equipped with humidity control.

Cleaning mode (Caleo® CleanSwitch™) simplifies the task of cleaning Caleo and must be used after ending operation of Caleo (see page 106), after the water supply has been disconnected and the water supply connection pipe has been removed (see page 110).

Cleaning mode may only be used if Caleo is empty.

Cleaning mode is activated from the control panel by pressing the "Menu" key and selecting the "Cleaning Mode" option.

In Cleaning mode, the water heater is forced to run dry. For this purpose, the humidifier is heated to above 100 °C (212 °F) for 20 minutes, so that all remaining water in the humidifier is evaporated. After the residual water has been evaporated, the temperature in the humidifier is maintained at a temperature above 100 °C (212 °F) for approximately another 10 minutes. Afterwards, the humidifier is allowed to cool down.

When there is no longer any danger of burns, a message is displayed on screen to inform the user that Cleaning Mode has concluded and that the incubator may now be dismantled for disinfecting and cleaning (see "After cleaning mode is complete", page 110).

Safety Systems

After switching on the incubator, it performs a self-test to check all memory addresses of the microprocessor control system and the proper running of all program segments. Functions of the control elements and feedback messages are tested by switching them on and off. This test is also performed at ten-minute intervals during operation. In this test, all modules installed in the incubator are tested. Any error message will be displayed even when the module found to be faulty was switched off at the time.

As a safety precaution, any non-permissible operating condition will cause Caleo to switch off its main heater or water heater, respectively.


An additional temperature sensor in the warm air vent limits heater output in cases where the heater control would generate maximum output over an extended period of time. Typical situations are, e.g., opening of access doors for an extended period of time, high setpoints (39 °C) in the presence of low ambient temperatures (<22 °C), or a partially obstructed warm air vent.

This safety feature significantly reduces the risk of burns caused by excessively hot surfaces in the area of the air vents or by vented warm air.

* Available option

Alarm Description

Visual signals on the control panel

- 1 Red alarm indicator LED
- 2 Yellow alarm indicator LED
- 3 Red power failure LED next to the  symbol


Caleo distinguishes between 4 different alarm priorities that are accompanied by audible alarms:

Serious device faults

Device fault:

- Continuous audible alarm that cannot be silenced, and
- 1 red alarm LED lighting up.

Power failure:

- Intermittent alarm tone that cannot be silenced, and
- 3 red power failure alarm LED next to the  symbol lighting up.

Warning (higher risk level)

- Alarm tone sequence (5 beeps), which can be silenced,
- 1 Red alarm LED blinking,
- central alarm light lighting up*, and
- measured value flashing.

For example:

- Skin 1 temperature above 39 °C

Caution (medium risk level)

- Alarm tone sequence (3 beeps), which can be silenced,
- 2 Yellow alarm LED blinking,
- central alarm light lighting up, and
- measured value flashing.

For example:

- Air temp. deviation above 1.5 °C

Advisory (low risk potential)

- 2 Yellow alarm LED lighting up.

For example:

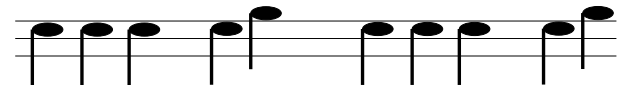
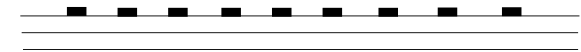
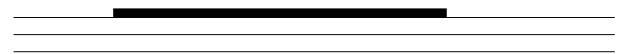
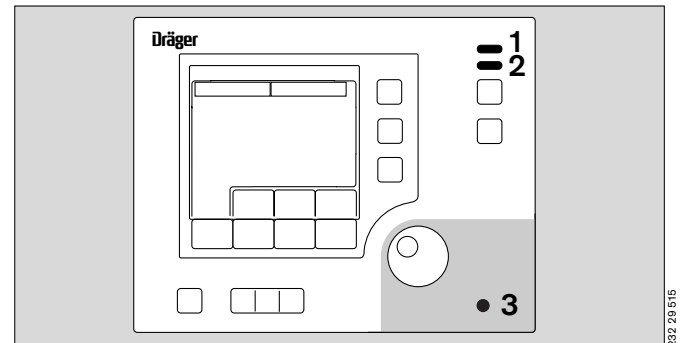
- Humidity deviation above 10 %

Information messages regarding the active alarm are displayed on screen.

If another alarm occurs while an audible alarm is silenced, the audible alarm will be reactivated.

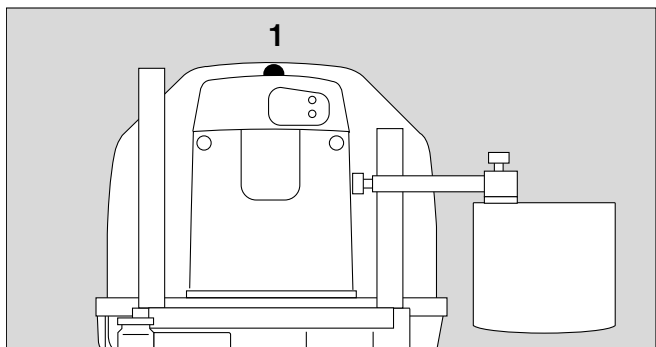
See "Suppressing Alarms", page 102.

* Central alarm light may be disabled.
See "Configuring system settings", page 97



Central alarm indicator light

- 1 The central alarm lights up whenever an alarm occurs.
-
- 1 The central alarm indicator does **not** light up with an alarm
 - if the alarm silencing key had been pressed, or
 - if the central alarm indicator has been deactivated in the Configuration. See "Configuring system settings", page 97.



Glossary

Key to Symbols Used



Alarm silence/suppression



Cancel, stop setting procedure



Weighing scale



Bed tilt



Bed can be pulled out



Radioscopy, x-ray drawer can be pulled out



Caution: please note special information on this function in the User Instruction Manual (this document).



Type BF



Keypad lock



Waiting for input from rotary knob

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Technical Data / Ordering Information

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Technical Data

Ambient Conditions

Normal operation

Temperature	20 °C to 35 °C (59 °F to 95 °F)
Air pressure	600 hPa to 1060 hPa
Rel. humidity	10 to 95 % without condensation

Storage / transport


Temperature	-20 °C to 60 °C (-4 °F to 140 °F)
Air pressure	210 hPa to 1060 hPa
Rel. humidity	10 to 95 % without condensation

Operating Data

Electrical power supply	100 V/120 V/127 V/230 V to 240 V (please specify in your order) 50 Hz/60 Hz
Max. power consumption at 100 V	10 A*
Max. power consumption at 120 V	8.7 A*
Max. power consumption at 127 V	9.1 A*
Max. power consumption at 230 V	5.5 A*
Max. power consumption at 240 V	5.6 A*
Leakage current 100 – 127 V / 50 Hz / 60 Hz	150 µA
Leakage current 230 – 240 V / 50 Hz	250 µA

Heater power	
Air heater	500 W
Water heater	140 W

Built-in power socket strip	
Max. permissible total power consumption for all sockets	2 A

 Max. leakage current:
By connecting devices to the power socket strip the overall leakage current may be increased to an unacceptably high level. Where applicable, national limits must be observed. The operator is responsible for adhering to the specified maximum overall leakage current.

Europe (IEC/EN 60601-1):	
Permissible overall leakage current	500 µA
Max. leakage current of the power strip	250 µA

USA (UL 2601-1):	
Permissible overall leakage current	300 µA
Max. leakage current of the power strip	150 µA

Height adjustment and tilting	
Duty cycle	10 %
Shut-off mode	6 minutes ON, 54 minutes pause (intermittent duty)

* Values include power consumption of the integrated power strip

Performance Data

Warm-up time	20 minutes from 20 °C to 31 °C (at 20 °C ambient temperature)
Increase in O ₂ concentration from 21 to 60 Vol.%	<10 min
Humidification	Evaporation of sterile distilled or demineralized water
Air speed over the bed	<8 cm/second (3.1 inch/second)
Fresh air flow	30 L/min
CO ₂ elimination according to IEC/EN 60 601-2-19 / 105.1 Max. CO ₂ concentration in the incubator	<0.5 vol.%
Bed tilting	Infinitely adjustable up to 13° tilt angle at both ends
Noise level inside the canopy	≤50 dB(A) at 50 Hz ≤50 dB(A) at 60 Hz
Particle filter	Particle class P2 conforming to IEC/EN 149 FFP2 pass volume 2 %

Measurement and Control Parameters

The specified values depend on ambient conditions

Air temperature control

Measuring principle	NTC, 2 x
Measuring range	13 °C to 42 °C (55.4 °F to 107.6 °F)
Measurement uncertainty	±0.8 °C (1.44 °F)
Setpoint range	20 °C to 39 °C (68 °F to 102.2 °F) in increments of 0.1 °C * <28 °C (82.4 °F) and >37 °C (98.6 °F), extended range (with confirmation)

Skin temperature control

Measuring principle	NTC
Measuring range	13 °C to 43 °C (55.4 °F to 109.4 °F)
Measurement uncertainty	±0.3 °C (0.54 °F)
Setpoint range	34 °C to 38 °C (93.2 °F to 100.4 °F) in increments of 0.1 °C >37 °C (98.6 °F), extended range (with confirmation)

O₂ control

Measuring principle	Electrochemical sensor (capillary)
Measuring range	18 vol.% to 99 vol.%
Measurement uncertainty	±3 vol.%
Cross-sensitivity	Humidity <1.5 %
Setpoint range	21 vol.% to 75 vol.% in 1 vol.% increments >40 vol.%, extended range (with confirmation) In rare cases the maximum actual value attained can be less than 75 vol.% but never less than 65 vol.%.

* Setpoint must be at least 3 °C (5.4 °F) above ambient temp. Under conditions of low ambient temperatures, high settings (39 °C) may not completely be reached. Use double wall.

Humidity control

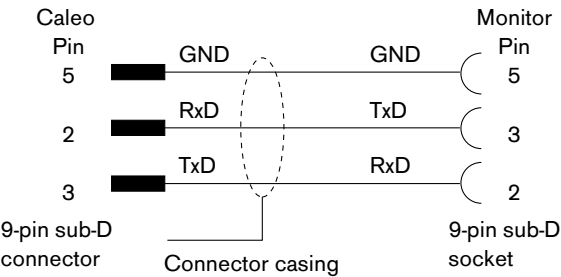
Measuring principle	Capacitive
Measuring range	10 % rel. humidity to 99 % rel. humidity
Measurement uncertainty	±10 %
Setpoint range	30 % rel. humidity to 99 % rel. humidity in 1 % increments*

Integrated infant scale

Measuring range	0 kg to 10 kg (0 lbs to 22 lbs)
Measurement uncertainty	±2 g (0.071 oz) from 0 kg to 2 kg (0 lbs to 2.2 lbs) ±5 g (0.176 oz) from 2 kg to 10 kg (2.2 to 22 lbs)
Resolution	1 g (0.035 oz)

BabyLink interface (optional)

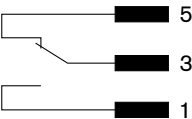
2 serial interfaces for output of incubator status data (measured values, setpoints, and alarms)
All signals are electrically isolated from the patient.
Dielectric strength 1500 V



08737054

Central alarm (optional)

Operating voltage	max. 24 V
Current	max. 250 mA
Power	max. 3 W
Potential-free changeover contact	



24323515

* Maximum humidity attained depends on air temperature and ambient humidity. With high ambient air temperature and low ambient humidity, respectively, the maximum humidity that can be reached inside Caleo will decrease.

Physical Characteristics

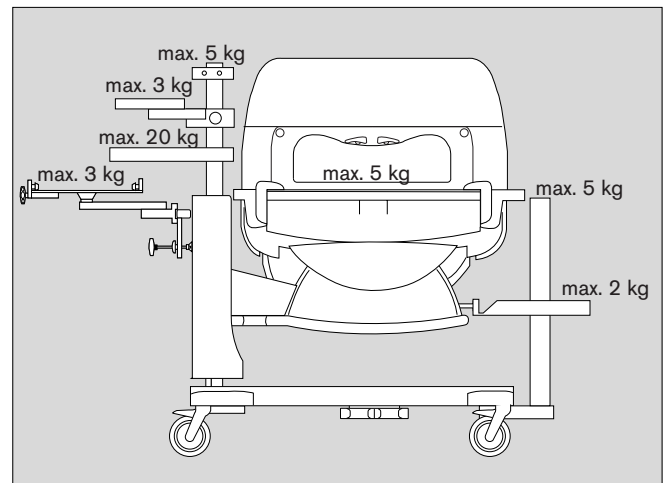
Dimensions

Incubator (width x depth)	1167 mm x 687 mm (45.9" x 27.0")
Height overall with height adjustable column	1220 mm to 1520 mm (48.0" x 59.8")
Height overall with fixed column	1270 mm / 1370 mm / 1470 mm (50" / 53.9" / 57.9")
Height of mattress surface (variable height)	800 mm (31.5") to 1100 mm (43.3")
Height of mattress surface (fixed height)	875 mm (34.4") / 950 mm (37.4") / 1050 mm (41.3"), depending on fixed height column installed
Bed (width x depth)	645 mm x 500 mm (25.4" x 19.7")

Weight

Overall weight	137 kg (302 lbs) (basic configuration)
Overall load capacity	60 kg (132 lbs)
Standard rail	10 kg (22 lbs) each
Pole extensions	14 kg (30.5 lbs) each
Monitor support/drawer/base pole	32 kg (71 lbs) overall

Overview of max. loads



Classification

according to EC Directive 93/42/EEC Appendix IX

Class IIb

UMDNS-Code

Universal Medical Device Nomenclature System

12-113

Standards

Enclosure protection class
Electromagnetic compatibility

Incubator conforms to IEC/EN 60601-1, IEC/EN 60601-2-19
I

tested to IEC/EN 60601-1-2 and
IEC/EN 60601-2-19 (36.202.2.1) 10 V/m

Skin temperature sensor

Type BF

Ordering Information

Incubator and Accessories

Designation and description	Part No.
Caleo	2M 50 555 /
Caleo incubator with air and skin servo modes, ThermoMonitoring™ (temperature probes optional). With large front and rear access doors, 6 extra large hand ports (Jumbo Ports™), detachable hood which opens to either side, electric bed tilt ($\pm 13^\circ$); 10 extra large tubing ports, integrated X-ray tray, integrated power strip (4 sockets), large graphic EL display with Draeger rotary knob, trend display and large numerical display, central alarm light.	2M 50 000
Available options	
Mobile stand with fixed height	Feature
Mobile stand with variable height	Feature
Servo controlled humidity	Feature
Servo controlled oxygen	Feature
Double wall	Feature
Integrated bed scale	Feature
Drawer	Feature
Interface (2xRS232, 1x nurse call)	Feature
Accessories for oxygen therapie	
Oxygen flowmeter, 32 L/min, 5 bar	2M 85 506
Silicone hose, connecting hose between Oxygen flowmeter 2M 85 506 and Caleo®	12 03 606
Oxygen connecting hose 3M (black)	M 29 233
Oxygen connecting hose 5M (black)	M 29 253
CS hose O2 DN6, 3/6M w/o connect.	M 30 873
MiniOx	2M 22 464

Designation and description	Part No.
Accessories for servo controlled oxygen	
DISS oxygen hose, 10 foot (available in USA)	45 30 807
O ₂ central supply system hose 3M NIST EN-F	86 02 514
O ₂ central supply system hose 5M NIST EN-F	86 02 515
CS hose O ₂ 3M, DIN-ST	M 34 402
CS hose O ₂ 5M, DIN-ST	M 34 403
CS hose O ₂ 5M without connector	M 34 416
Oxygen hose 5M NIST, SW, w/o connect.	M 32 037
Adapter O ₂ DIN/NIST	M 32 366
Oxygen CS hose 3M DIN BL	M 29 231
Oxygen CS hose 5M DIN BL	M 29 251
Shelves, holders, infusion accessories	
Monitor shelf	2M 50 085
Swivel table	2M 21 186
Pole 38/600	2M 50 691
Pole 38/310	2M 50 688
Pole 25/600	2M 50 689
Base pole	2M 50 680
Infusion support, 38 mm pole	2M 21 514
Rail-mounted infusion holder	2M 20 719
Compact rail	2M 85 337
Tray 3020	M 24 678
Notebook holder	2M 22 171
Accessories for bed area	
Ventilation circuit support arm	84 11 075
Caleo SoftBed™	MX 17 012
Accessories for phototherapy	
Phototherapy 4000 (220-240 V)	2M 21 000
Phototherapy 4000 (110-127 V)	2M 21 700
Phototherapy 4000 (100 V)	2M 22 090
Stand for phototherapy unit 4000	2M 21 190

Ordering Information

Incubator and Accessories

Designation and description	Part No.
Accessories for secretion aspiration	
Bronchial aspiration, -0.5 bar	2M 85 125
O ₂ – Air connection hose, 3M (black)	M 29 245
O ₂ – Air connection hose, 5M (black)	M 29 265
Air/O ₂ CS hose, 3M DIN	M 29 243
Air/O ₂ CS hose, 5M DIN	M 29 263
Wire basket 510	M 24 670
Wire basket 300	M 26 145
Wire basket 600	M 25 121
Holder for litter bags	M 24 695
Set of 100 litter bags	M 26 240
Upgrade kits	
Servo controlled humidity	2M 50 735
Servo controlled oxygen	2M 50 740
Bed scale, integrated	2M 50 745
Double wall	2M 50 421
Drawer	2M 50 565
Interface, RS 232	2M 50 750
Technical Documentation	on request

Replacement Parts

Designation and description	Part No.
Spare parts and consumables	
Water reservoir, complete	2M 50 040
Cap for water reservoir	2M 50 042
Nozzle for water reservoir	2M 50 039
Infusion sets Caleo (20 pcs)	MX 17 018
O-ring, for water connection pipe	2M 50 346
Caleo air intake filter (20 pcs)	MX 17 015
ThermoTrace™, central (set of 5), yellow	MX 11 000
ThermoTrace™, peripheral (set of 5), white	MX 11 001
ThermoPad™ (set of 50)	MX 11 002
Oxy-Trace™ Incu.	MX 01 050
Tubing grommets, large	2M 50 385
Tubing port	2M 50 412
Feeding grommet, hood	2M 50 352
Caleo standard mattress	2M 50 556
Caleo SoftBed™	MX 17 012
Vacuum mattress	2M 17 909
Lithium batteries, 3V/ 1400 MAH	18 35 343
Mattress cover (blue-nose kitten design)	2M 21 272
As an alternative to the part numbers listed above, the following parts and devices, which are no longer supplied by Draeger, may be used.	
Adhesive pads	2M 21 735

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These Instructions for Use apply only to **Caleo®** with Serial No.:

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